5-2000

Effects of High Fruit Intake on Systematic Blood Pressure in African Americans

Leonard L. Gibbons

LOMA LINDA UNIVERSITY
School of Public Health

EFFECTS OF HIGH FRUIT INTAKE ON SYSTEMIC BLOOD PRESSURE IN AFRICAN AMERICANS

by

Leonard L. Gibbons

A Dissertation in Partial Fulfillment of the

Requirements for the

Degree of Doctor of Public Health

in Preventive Care

May, 2000

Each person whose signature appears below certifies that this dissertation in his opinion, is adequate in scope and quality as a dissertation for the degree Doctor of Public Health.

Glen Blix, DrPH, Chairperson
Associate Professor of Health Promotion and Education, SPH

Susanne Montgomery, PhD
Professor of Health Promotion and Education, SPH

Warren Peters, MD, MPH
Associate Professor of Health Promotion and Education, SPH

ABSTRACT OF THE DISSERTATION

Effects of High Fruit Intake

on Systemic Blood Pressure in African Americans

by

Leonard L. Gibbons

Degree of Doctor of Public Health in Preventive Care

Loma Linda University, Loma Linda California, 2000

Professor Glen Garry Blix, Chairperson

This randomized dietary intervention trial examined the effects of a high fruit diet on systemic BP in African-Americans. Thirty-eight free-living subjects with systolic BPs between 130-159 mm Hg and diastolic BPs between 85-99 mm Hg, were enrolled for a six week period. The cases were given daily supplements of potassium rich foods: bananas, orange juice and raisins, while no dietary advice or food was given to the controls.

After six weeks, the means systolic BP was 5.79 mm Hg (p=.009) lower in the cases than the controls. The mean diastolic BP at week six was 3.76 mm Hg (p=.047) lower in the cases than the controls. Analysis of the study participants who had mild hypertension, revealed a mean reduction in systolic and diastolic blood pressure after six weeks of 12.6 mm Hg (p=.131) and 6.53 mm Hg (p=.014) respectively in the cases when compared to the controls. The systolic BP drop for the

cases was significant at 14.42 mm Hg ($p=.02$) after three weeks. High levels of fruit intake (6 to 8 servings/day) was correlated with a significant ($P<.05$) mean drop in blood pressure (6 to 8.19 mm Hg) in the cases when compared to the controls who consumed one or fewer servings of fruit per day.

The results of this study suggest that a diet high in potassium rich fruits such as bananas, orange juice and raisins is an effective approach to lowering BP in individuals with mild hypertension.

TABLE OF CONTENTS

LIST OF TABLES

LIST OF FIGURES

ACKNOWLEDGEMENTS

First and foremost, I wish to thank my Heavenly Father for life, health, wisdom and the desire to be a change agent in His cause to restore mankind- body, mind and spirit.

I wish to thank the health professional and friends who volunteered their time to help me during the assessment, intervention and analysis phases of this dietary study.

I would like to thank Dr. Glen Blix, Dr. Warren Peters and Dr. Suzanne Montgomery for their support, encouragement, guidance and timely advice throughout this dissertation process. I wish to thank Dr. Tony Frankson for his patience, guidance and statistical expertise. I am thankful to Dr. Ella Haddad for her guidance and expertise in the analysis of the urinary values.

I wish to thank my wife Rosamund, who supported and encouraged me to complete this project, and our children, Ryan and Lindsay who provided a pleasant diversion from this tasking endeavor. Thanks to my parents, Mr. and Mrs. Ivan Gibbons, who have encouraged and supported me through each stage of my education.

I wish to thank the pastors and church members of San Bernadino Christian Centre, Temple Missionary Baptist Church and Ecclecia Christian Fellowship for their support and participation in this research project.

Finally, I wish to thank the following food companies for the fruit they donated for this research project. Dole Fresh Fruit Company for the bananas, California Raisins for the raisins and Agrigold Juice Products for the orange juice.

CHAPTER 1

INTRODUCTION

A. Definition of the Problem

Hypertension is associated with an increased risk for coronary heart disease, stroke, congestive heart failure, renal insufficiency, and peripheral vascular disease. Based on data collected from NHANES III (Phase 1), high BP ($\geq$140/90) affects at least 50 million people, or one in every four adults in the United States. (The Fifth Report of the Joint National Committee on Detection, Evaluation and Treatment of High Blood Pressure, 1993). Hypertension appears at an earlier age, is more prevalent, is more likely to be associated with end-organ complications, and is less likely to be treated with traditional therapies in African Americans compared to European Americans (Lackland et al., 1996). Large segments of the population with BP levels not defined as hypertensive are at increased risk for coronary vascular disease. Optimal BP levels are less than 120 mm Hg systolic and less than 80 mm Hg diastolic.

Data from the NHANES III (Phase 2) population samples indicates that 68.4% of the individuals with high BP are aware of a diagnosis of hypertension, 53.6% of those with hypertension were receiving medication, and only 27.4% of those receiving anti-hypertensive medication have BP levels less then 140/90 mm Hg. (The Sixth Report of the Joint National Committee on Detection, Evaluation and Treatment of High Blood Pressure, 1997). Although these single visit measurements may have exaggerated the extent of hypertension in the community, they do suggest that large numbers of hypertensive patients are unaware of their diagnosis and that many who are being treated for hypertension, probably have sub-optimal BP control. Further, approximately 2 million new hypertensive patients are added to the pool of patients requiring treatment for high BP each year (Stamler et al., 1993; The Fifth Report of the Joint National Committee on Detection, Evaluation and Treatment of High Blood Pressure, 1993 & Working Group Report on Primary Prevention of Hypertension, 1997).

Populations in non-industrialized societies generally have lower BPs which rise minimally with age when compared to the U.S. and other industrialized societies. Diet is one factor that is related to this difference. Further, both population studies and experimental control studies indicate that BP levels decrease as the diet composition changes from an omnivore pattern to lacto-ovo-vegetarian and vegan diets with increased intakes of fruit, vegetables, grains and legumes (Sacks, & Kass, et al., 1974 & INTERSALT Cooperative Research Group, 1988). The levels of potassium and magnesium in these foods may be related in part to these differences in BP levels across different populations.

The results from a number of studies suggest that potassium intake may have a role in preventing high BP (Meneely & Battarbee, 1976; Page et al., 1981 & Frisancho et al., 1984). These studies identify an inverse relationship between BP and dietary potassium. One trial conducted in Africa and several trials in subgroups in the United States are consistent with the idea that African-Americans may derive particular benefits from potassium supplementation (Kaplan et al., 1985; Matlou et al., 1986; Siani et al.,1987; Obel, 1989 & Smith et al., 1985). Many African Americans consume low intakes of potassium rich foods. The potassium intake for African-American men aged 45 to 74 years corresponds to the lowest 10th percentile of daily potassium intake of all U.S. men (30 to 39 mmols) and the lowest 25th percentile in all U.S. women (34 to 36 mmol) (Brancati et al., 1996). Brancati et al., (1996) have suggested that an increase in potassium intake might represent an inexpensive, safe, and effective approach to reducing BP in African-American adults who consume a diet low in potassium.

There is evidence that suggests that a low intake of dietary magnesium may be associated with an increased risk for high BP (Craig, 1992). In the Honolulu Heart Study a lack of magnesium had the strongest association with elevated BP (Joffres et al. 1987). Ascherio et al., (1996) identified a significant inverse association between magnesium intake and systolic and diastolic BP in the female participants.

While a few studies have shown significant drops in BP, several clinical trials have not verified these findings. According to Whelton et al. (1989), it may be difficult to interpret the data from these magnesium supplementation trials because anti-hypertensive medication was used and the studies were relatively short. However, in phase 1 of the Trials of Hypertension Prevention, magnesium supplementation produced no significant improvements in BP for the 461 participants after a six month time period (Working Group Report on Primary Prevention of Hypertension, 1993).

Clinical trials that have combined specific nutritional supplements - magnesium, sodium and potassium (Geleijnse et al., 1994) or increased consumption of legumes, fruit and vegetables (Siani et al., 1991), or increased consumption of fruit intake alone (Singh et al., 1993, 1995), have identified significant BP drops in the hypertensive participants under active treatment.

B. Purpose of the Study

This research evaluated the blood pressure lowering effect of increased intakes of bananas, orange juice and raisins in 38 free living African-Americans with systolic BPs between 130-159 mm Hg and diastolic BPs between 85-99 mm Hg over a six-week period. We hypothesized that high intakes of fruit containing moderated to high quantities of magnesium and potassium would produce a BP lowering effect that is statistically significant and comparable to levels achieved in supplementation trials. These benefits would be achieved without promoting weight loss, increased physical activity or sodium restriction.

C. Research Question

Can a six-week diet with high intakes of fruit containing moderate to high quantities of magnesium and potassium lower blood pressure in healthy African-Americans with systolic BPs between 130-159 mm Hg and diastolic BPs between 85-99 mm Hg?

D. Importance to Preventive Care

The importance of this research to the field of Preventive Care cannot be over-emphasized. Hypertension in a disease that can be addressed though preventive lifestyle measures. It has been estimated that a population wide drop in systolic BP of 3 mm Hg could reduce the annual mortality from stroke, CAD and all causes by 8%, 5% and 4% respectively. Results from clinical trials utilizing non-pharmacological interventions for individuals with high normal BP, indicate that targeted interventions that lower diastolic BP by as little as 1 to 3 mm Hg may reduce the incidence of hypertension by as much as 20% to 50% (Working Group Report on Primary Prevention of Hypertension, 1993).

Lifestyle therapy is an effective means of reducing the complications associated with the long-term use of drug therapy in the treatment of hypertension. In one study, the experimental participants (high fruit and vegetable diet) reduced their dependence on medication by 50% compared to 29% of patients in the control group. At the end of the 1-year follow-up 38% of high fruit and vegetable consumers had well controlled BP without any drug therapy compared with 9% in the control group (Siani et al., 1991).

E. Theoretical Foundation

The results from a number of studies suggest that potassium and magnesium may decrease BP levels in individuals with hypertension. Potassium may produce its effect on BP through natriuretic effects, suppression of renin-angiotensin and sympathetic nervous systems, improvement of baroreceptor function and reduction of peripheral vascular resistance by direct arterial vasodilatation. Magnesium plays a major role in numerous homeostatic processes. It is also a vasodilator (Working Group Report on Primary Prevention of Hypertension, 1993).

CHAPTER 2

LITERATURE REVIEW

Cross-sectional epidemiological studies suggest that vegetarians have lower blood pressures (BP) and less of a rise in BP with age than meat eaters. Controlled dietary intervention trials of mild hypertensive and normotensive individuals provide more direct evidence of the beneficial effects of vegetarian diets in lowering BP. These BP effects are independent of both weight loss and levels of dietary sodium intake. Studies designed to identify a number of nutrients possibly involved suggest that no one nutrient is independently responsible. This review of the literature addresses these findings and formed the basis for this research project on diet and BP control in African-Americans.

A. Nutritional Therapy-The Present Guidelines

The Hypertension Control Program-a four year randomized controlled trial, assessed whether less severe hypertensives could end antihypertensive drug therapy by using nutritional means to control blood pressure (Stamler et al., 1987). After four years, 39% of the group that had a nutritional program (including weight reduction and salt and alcohol restriction) remained normotensive without drug therapy, compared with 5% in the group that discontinued therapy with no nutritional program. A third group continued drug therapy without making dietary changes.

This study of 189 patients demonstrated that nutritional therapy could be substituted for drug treatment programs in selected hypertensive individuals, while others can reduce the amount of medication required to maintain acceptable BP levels. Possible threats to validity-though with little effect on this study- include under reporting on seven-day food diaries and falsely reporting changes in alcohol use and other lifestyle habits. The highly significant results of this study support the idea that any variation from the study protocol was too weak to demonstrate differences between the groups. These results are consistent with the data from the one year Dietary Intervention Study in Hypertension (Langford et al., 1985).

The Treatment of Mild Hypertension Study conducted by Neaton et al. (1993) underscored the importance of combining nutritional-hygienic interventions with drug treatment in controlling hypertension. In a four-year randomized, double blind, placebo-controlled clinical trial, researchers advised all participants to reduce weight, dietary sodium intake, alcohol intake, and to increase physical activity. Participants were randomly assigned to one of five different drug treatment groups or a placebo group. After four years, 59% of the participants assigned to the placebo and 72% of the participants given the drug treatment continued their initial treatment program. Although, the drug treatment in combination with the nutritional-hygienic intervention was significantly more effective in preventing unwanted clinical events than the nutritional-hygienic treatment alone, it is important to note that nearly 60% of the hypertensive patients in the placebo group (n=234) controlled their BP without drug therapy.

A dietary approach to treating mild hypertension (weight reduction, sodium restriction, limiting alcohol intake and maintaining adequate intake of dietary potassium) is in line with the recommendations of the Joint National Committee report regarding treatment choices for people with stage 1 ("mild") hypertension. They advise that such individuals should receive lifestyle modification as the sole initial intervention for up to 6 months, provided the patient has no target organ damage, diabetes or clinical cardiovascular disease. If a systolic BP of less than 140 mm Hg and a diastolic BP of less than 90 mm Hg cannot be achieved, the treatment programs warrants the addition of anti-hypertensive drugs (The Sixth report of the Joint National Committee on Detection, Evaluation and Treatment of High Blood Pressure, 1997).

B. Vegetarian Diets and Population Data

The differences in BP of populations worldwide is quite evident and striking (Sacks, & Kass, et al., 1974 & INTERSALT Cooperative Research Group, 1988). Blood pressure levels are higher and rise more steeply with age in industrialized societies than in non-industrialized societies. A predominantly vegetarian dietary pattern is often present in the cultures that generally have low BP levels. Epidemiological surveys on BP levels in population groups in the U.S., Europe, Japan, China, India, Malaysia, Australia, and the South Pacific Islands show trends linking diets with little meat and fish to low mean BP among the inhabitants. Although these cross-sectional studies cannot establish causation, they do suggest that nutritional factors play a role in determining BP levels.

The Trappist Monks of Holland and Belgium have a lower incidence of diastolic hypertension (21 or 12%) then the Benedictine Monks (51 or 30%) (Groen et al., 1962). Diastolic hypertension was defined as 95 mm Hg or higher. The lifestyle of these monks was very similar from the psycho social aspect, but three differences existed between the two orders: (1) The Trappist monks hardly heated their monasteries; no such rule exists among the Benedictine monks; (2) The Trappist monks communicated by code and spoke only when given permission, while the Benedictine monks spoke freely among themselves; (3) The Benedictine monks consumed an average western diet while the Trappist Monks are strict vegetarians. The Trappist Monks, unlike the Benedictine monks, impose on themselves a religious fast during winter and early spring which reduces their daily calorie intake by nearly 50%. One may suggest that these differences influenced the BP variations in these orders.

However, it is not clear to what extent these results can be attributed to diet alone. Several known confounding factors include differences in stress level, lack of random selection of subjects, age differences and overall weight between the two groups. Further, the very nature of an observational study precludes establishing causation. The association observed my be due to a number of seemingly unrelated factors.

The most convincing population data concerning a BP lowering effect of vegetarian diets comes from studies of Seventh-day Adventists (SDA). The BPs of 418 vegetarian SDA in Western Australia were compared with those in 290 non-vegetarian non-SDA volunteers in Narrogin, a Western Australian country town (Armstrong et al., 1977). After adjusting for age, sex, height and weight, the BPs of the SDA (128.7/76.2 mm Hg) were significantly less than the Narrogian residents (139.3/84.4 mm Hg). These differences do not appear to be due to the differences in tea, coffee or egg consumption, socioeconomic status, alcohol, tobacco, or physical activity. However, selection bias may have operated to bring a sicker sample of Narrogians than it did at the SDA convention. The SDAs who were sicker may have avoided the study for fear their less then ideal health status would be discovered, while a similar population of Narrogians may have chosen to join the study in hopes of improving their health status. Chance must be ruled out as the entire reasons for the differences in blood pressure between the SDAs and the Narrogians given the significant difference ($p<0.001$) between the two groups. Unmeasured environmental differences between these two groups may also explain the difference between BP in the two groups. Another potential confounder might be the stress reducing effects of religious beliefs.

Another population study involving SDAs compared the relationship between BP in Black and White adults SDAs at two conferences (Melby et al., 1989). Regarding the use of BP medication, 44% of the Black non-vegetarians were on BP medication compared to only 18% of Black vegetarians. Twenty-two percent of the White non-vegetarians were on BP medication compared to only 7% of the White vegetarians. After adjusting for age, sex, body mass index and waist/hip ratio, the systolic BP among Black vegetarians remained lower. The BP among Whites showed no diet-related differences between vegetarians and non-vegetarians. This result may be due to the more prudent diet eaten by White SDA non-vegetarians.

Similar to the previous study, selection bias may have operated to bring a sicker sample of non-vegetarians and a healthier sample of vegetarians. Vegetarians and non-vegetarian SDAs may differ systematically in attributes not measured by this study which might impact BP. It also appears that the impact of the vegetarian diet did not rule out race as a factor in the prevalence of hypertension.

The Child-Adolescent Blood Pressure Study compared the BP levels in SDAs and non-SDA children who attended grades one through ten in 29 Southern California schools (Harris et al., 1981). Despite the marked differences in life-style between the two groups and the fact that adults from the two population groups have marked differences in mortality due to hypertension, the analysis of the data failed to show significant differences. Black children of both sexes and all ages had a slightly higher mean BP.

These results may be due in part to fact that 10% of non-SDA students attend SDA schools and fewer than 5% of SDA students attend public schools. Another possible confounder may be that less marked differences are among SDA vs. non-SDA young people as compared to differences between their parents. However, the data does not confirm this effect. A third explanation may be that the effects of lifestyle on BP have a delayed effect, which appears later in life.

A detailed comparison study of BP and lifestyle compared 98 SDA lacto-ovo-vegetarians with 82 SDA omnivores and 113 Mormons omnivores (Rouse et al., 1983). After adjustments for age, height, and weight the mean BPs of the SDA vegetarians were significantly lower than the Mormon omnivores. These differences were unrelated to current or past use of alcohol, tea and coffee, personality characteristics, physical activity, or degree of religious observance. The prevalence of mild hypertension ranged from 10% in the Mormons, 8.5% in SDA omnivores and 1-2% in SDA vegetarians. Analysis of the diet records revealed that SDA vegetarians ate significantly more magnesium, potassium, vitamin C, fiber, polyunsaturated fatty acids, and vitamin E, and significantly less total fat, saturated fatty acids, cholesterol, vitamin B-12 and iron compared to the Mormon omnivores.

The results of 24-hour urinary excretions for both groups indicated that the BP differences were unlikely due to dietary sodium. Although the possibility of a bias being introduced in this study through more healthy SDA volunteers and more unhealthy Mormon volunteers, it seem unlikely that such an effect accounted for most of the BP variation seen in this study. Perhaps other unidentified factors contributed to the blood pressure differences. The BP differences between Mormon omnivores and SDA vegetarians could imply that something in the vegetarian diet is responsible for these BP effects.

In a cross-sectional longitudinal study covering a ten year period, diet histories and blood pressures were taken of middle aged men in the town of Zutphen in the Netherlands (Kromhout et al., 1985). The researchers in this study found that potassium intake was significantly inversely related to systolic BP in 1970, calcium intake was significantly inversely related to BP in 1965 and 1970, and alcohol intake was significantly positively related to changes in BP in 1960, 1965, 1970, and during 5 year follow-ups. It is unclear whether the changes in dietary intake of potassium and calcium affected the blood pressure at these different time periods. There were too many uncontrolled factors in this study. Further, no accurate information was obtained on the use of anti-hypertensive medication or salt added to food.

In a prospective study by Ascherio et al. (1996), the relationship between nutritional factors and blood pressure among 41,541 predominantly white U.S. female nurses (without hypertension) was examined during 4 years of follow-up (1984 to 1988). In the 2,526 women who reported a diagnosis of hypertension during the follow-up, age, alcohol consumption and relative weight were the strongest predictors for the development of hypertension. Among women who did not report hypertension during the follow-up, potassium, magnesium, calcium and fiber were significantly inversely associated with self-reported systolic and diastolic pressures, after adjusting for BMI, alcohol consumption, energy intake and age. These four nutrients were not significantly associated with risk of hypertension after adjusting for BMI, age, alcohol, and energy intake for the women with hypertension. After simultaneously adding the four nutrients to the regression model, only fiber and magnesium intakes retained significant inverse association with BP. The fruit and vegetable intake of study participants was inversely associated with systolic and diastolic pressure. Despite the limitations of this study in defining which nutrients do in fact lower BP, these findings suggest that magnesium and fiber, as well as a diet richer in fruits and vegetables may reduce blood pressure levels.

The final population study reviewed in this dissertation addressed sodium and potassium intake and blood pressure change in childhood. A longitudinal population study of 233 children from the Netherlands (age 5-17) were randomly selected and tested for sodium and potassium excretion at six annual periods and compared for changes in BP (Geleijnse et al., 1990). The researcher in this study excluded hypertensive individuals and made adjustment for sex, age, height, and body weight over time. The results of 6 annual 24-hour urine analysis for sodium and potassium revealed a strong and inverse association between potassium excretion and systolic BP. The systolic BP slope was higher when the sodium to potassium ratio was steeper. This study suggests that dietary potassium and the sodium to potassium ratio may be important in the pathogenesis of hypertension. Proof of an association will need to come from controlled studies that rule out many unknowns in population based studies.

This review of several populations studies regarding vegetarian diets and BP control, suggests that vegetarians have lower BP then non-vegetarians. The mean BP levels of a number of people group's worldwide support this finding. Several studies with tighter controls and analysis have suggest a number of nutrients, including potassium and magnesium, as being possibly responsible for the antihypertensive effect of vegetarian diets. The beneficial effect of vegetarian diets are not as pronounced between white and black SDA with regard to BP control. The impact of diet on BP control seems to be delayed until late teen and early adulthood. While these comparison studies cannot prove cause-and-effect relationships, the proof of such a relationship can be determined through randomized controlled dietary intervention trials.

C. Vegetarian Diets and Intervention Trials

A randomized controlled dietary cross-over intervention trial conducted at the Royal Perth Hospital involved the introduction of a lacto-ovo-vegetarian diet to healthy meat eaters (Rouse et al., 1983). Fifty-nine hospital employees were assigned to one of three groups after matching of age, sex, and obesity. After a familiarization period for both groups (2 weeks), the control group continued a normal meat diet, while a second group ate a lacto-ovo-vegetarian diet for 6 weeks and then returned to a normal meat diet for another 6 weeks. The second group at the normal meat diet for 6 weeks and then changed to the lacto-ovo-vegetarian diet for 6 weeks. Mean systolic BP remained unchanged for the control group but fell significantly in both experimental groups during the vegetarian diet and rose significantly when they reverted to a normal meat diet. A diet related fall in BP of 5-6 mm Hg systolic and 2-3 mm Hg diastolic was achieved. All participants were requested to maintain their present lifestyle practices during the life of the study. Compliance to the diets was confirmed by laboratory measurements of an amino acid protein found predominantly in meat protein.

One limitation of this study may be that the subjects were highly motivated, quite unlike the general population. A second limitation is that the experimental subjects were not blind to the different diet. Hence, some awareness of the hypothesis could have influenced the BP in the desired direction. However, the subjects were quite eager to resume a meat diet, which suggest greater stress during the vegetarian phase of the experiment. The changes in BP in this study did not suggest a relationship between sodium and potassium excretion. Perhaps it may take longer for such an effect to be seen with the levels of these minerals consumed by the study subjects. This study confirms a diet related fall in BP but failed to identify the nutrient involved.

Margetts et al. (1986) conducted a randomized crossover trial of 58 subject that was similar to the previous study. The major differences in this study were that all subjects were untreated mild hypertensives. The subjects prepared all their own meals and were asked to take a small dose (50 mg) of one vitamin C tablet daily with the understanding that the researchers wanted to know if vitamin C could reduce BP with or without a vegetarian diet (hoping to reduce the placebo effect of the vegetarian diet). The principle nutrient intakes were compared for subjects on both diets. A significant fall in systolic BP pressure of 5 mm Hg occurred during the vegetarian diet and rose again during the meat eating diet. The change in diastolic BP during the vegetarian diet was insignificant at 1.3 mm Hg. Significant increases of nutrients during the vegetarian diet included the ratio of polyunsaturated to saturated fats (80%), dietary fiber (35%), vitamin C (56%), vitamin E (32%), calcium (19%) and magnesium (17%). Intake of vitamin B 12 (56%) and protein (19%) decreased while potassium intake did not change.

Despite these favorable results, some subjects in this study may have not been blind to the reasons for the dietary intervention. Subjects may have read or heard about the subject of BP control and diet which may have influenced their belief in its effectiveness and consequently the positive outcomes. In spite of this possibility, it is unlikely that the placebo effect was largely responsible for these results given the significant differences in BP outcomes and dietary nutrient increases between the two dietary phases in this study.

These findings are consistent with evidence from cross sectional population studies that suggest a BP lowering effect in vegetarian diets. These effects have been produced without changing levels of sodium intake. Although the vegetarian diet would be the ideal approach to reduce the incidence of hypertension from a population standpoint, the search continues to discover the specific dietary components that produce these effects.

Researchers are looking for specific nutrients or combinations of nutrients that are responsible for the anti-hypertensive effects seen in vegetarian diets. To do this, they study the effects of single nutrients or combinations of nutrients in hopes of ruling out nutrients that have no effect on BP and discovering the nutrients that do.

D. Nutrients and Clinical Trials

Several studies have tested the hypothesis that a high intake of protein is related to hypertension. Twenty-one strict vegetarians in one control study were studied for an eight-week period. The study began with a two-week control period on the usual vegetarian diet followed by four weeks during which 250 g of beef was added to the daily vegetarian diet followed by two weeks on the control diet (Sacks et al., 1981). The systolic blood pressure increased significantly during the meat eating period by 3% over the control values. The subjects who volunteered for this study ate all of the prepared beef and some of the vegetarian dishes at the study site. These subjects were asked not to alter their usual vegetarian meals during the usual mixed diet, and to keep the meat as the only change in diet during the eight weeks.

Although this study had good controls, adverse mood factors (anxiety, depression, anger, fatigue, confusion) were significantly higher during the meat stage as compared with the positive factor, vigor, during the two vegetarian stages. This effect may have added to the systolic BP. However, the researchers noted that the effect of this mood score lost its significance when either BP or pulse rates was added to the regression model used in this study.

Sacks et al. (1984) found no effect of BP reduction of a low protein (63 g) rice patty supplemented diet when compared with a high protein (119 g) soy-wheat patty supplemented diet during a 6-week periods in a 2-group crossover design. Changes in other major nutrients, mean body weight, and sodium and potassium excretion were not significant. The researchers concluded that protein intake, when consumed in the amounts in this study, had no short-term effect on BP. It is unlikely that the self administered food frequency questionnaire were significantly different from actual intake when we consider the small changes in major nutrient intakes (besides protein) over the life of this study. However the effect of the vegetable protein on BP may be quit different from the effect of beef protein which was addressed in the previous research.

To control for any confounding effects produced by the ingestion of meat, Sacks et al. (1984) conducted a three month study with 19 normotensive meat eaters (men and women) who adhered to a diet that eliminated poultry, meat, eggs and dairy fat while keeping the consumption of polyunsaturated fatty acids, carbohydrates, and dietary fiber unchanged. No significant changes were seen in BP, body weight, or in sodium and potassium excretion. Because of the open blind nature of this study, the placebo effect of anticipated benefits could have influenced the results. However, the lack of a BP effect rules out this possibility. The only significant change in nutrient intake was a decrease in protein.

Another nutrient of concern in the vegetarian diet with regard to BP control is the type of dietary fat. In a randomized, double blind, crossover protocol, 21 untreated mildly hypertensive patients replaced dietary saturated fat with either carbohydrate or polyunsaturated fat (linoleic acid). Patients received, over a six-week period, cream, safflower oil and carbohydrate in random sequence; each prepared in flavored yogurt or milk with a four-week washout period between supplements. In this study the researchers used the Armitage and Hills approach which found no evidence of a carry over effect on BP from one supplement to the next. No significant changes in BP were found during the three dietary periods. The type of fat eaten doesn't appear to effect the blood pressure levels of hypertensive subjects.

Another factor considered in the BP control is the ratio of polyunsaturated fats to saturated fats in the diet. In a randomized trial 57 couples were randomly allocated to one of three groups after a two week baseline period. A low fat diet with a high polyunsaturated to saturated (P/S) ratio, a reduced salt group (from 192 mmol to 77 mmol), and a group that continued the usual diet (Puska et al., 1983). All groups received equal amounts of time and support from the study team. After the six-week intervention the group with the highest P/S ratio experienced a decline in systolic BP from 138.4 to 129.5 mm Hg and diastolic BP from 129.5 to 88.4 mm Hg during the intervention period. These values rose again during the switch back period. No significant changes in BP were observed in the other two groups.

These effects could not be explained by weight reduction, salt intake, other lifestyle changes or a measurement effect. However, it is not clear which element of the diet caused the change in BP. The subjects in the group with the high P/S ratio received a high intake of vegetables during the intervention period. These dietary changes were not provided for the other groups. Hence, some elements in the vegetables may have been responsible for the fall in BP.

A more tightly controlled cross over design trial, found no such relationship between the P/S ratio and changes in BP levels. Fifty-four healthy omnivore normotensive volunteers were randomly assigned to a control group eating a low P/S ratio diet throughout the study, or one of two experimental groups eating a high P/S ration diet for two six week experimental periods (Margetts et al., 1955). There were no significant changes in any dietary component of the three groups besides the P/S ratio. Further, measures of weight, urinary sodium or potassium, plasma lipids, smoking, alcohol and exercise did not explain the lack of association between dietary P/S ratio and BP in this study. It is quite possible that the association between P/S ratio and BP as found in the previous study and in another by Iacono et al. (1983) may have been due to the large dietary increases of fruits and vegetables. This idea supports the findings of a number of studies reviewed previously.

There is some evidence that suggests that a low intake of magnesium may be associated with an increased risk for high BP. Hypertensive individuals have been reported to have reduced intakes of magnesium when compared to normotensive individuals (Craig, 1992). A few studies have shown significant drops in BP while others trials have not verified these observations. It may be difficult to interpret the data from these magnesium supplementation trials because antihypertensive medication was used and the studies were relatively short (Whelton et al., 1989). However, in phase 1 of the Trials of Hypertension Prevention, magnesium supplementation produced no significant improvements in BP for the 461 participants after a six-month period (Working Group Report on Primary Prevention of Hypertension, 1993).

A double blind cross-over study consisted of one-month treatment period with magnesium aspartate (15 mmol/day), followed by one month with placebo. The researchers found no evidence of a BP lowering effect of dietary magnesium (Cappuccio et al., 1985). Seventeen patients with mild to moderate hypertension did not alter their diets during the treatment and placebo phases which consisted of two tablets three times a day. The only significant change observed was the change in plasma and urinary magnesium levels during the magnesium supplementation periods. Due to the short length of this study, definite conclusions cannot be drawn about the long-term effects of magnesium supplementation on BP control. In The Trials of Hypertension Prevention phase 1 study 15 mmol/day magnesium (tablets) over a six month period resulted in an insignificant drop in BP (-0.2/-0.1) (Working Group on Prevention of Hypertension, National High Blood Pressure Education Program, 1993).

However, the results in the Honolulu Heart Study indicate that magnesium as well as potassium, calcium and fiber were inversely associated with both systolic and diastolic BP levels of men of Japanese ancestry living in Hawaii who had no history of CAD. Multivariate analysis revealed that a lack of magnesium had the strongest association with elevated BP (Joffres et al., 1987). Perhaps the positive effects of magnesium on blood pressure control is the result of consuming magnesium along with other specific nutrients not accounted for is the magnesium supplementation trials.

The results from a number of studies suggest that potassium supplementation may have a role in lowering elevated BP. A pooled analysis by Whelton et al. (1992) of 16 randomized controlled trials conducted in hypertensive patients identified an overall reduction in systolic BP and diastolic BP of -5.1 mm Hg (95%CI, -6.3 to -3.8 mm Hg) and -3.0 mm Hg (95% CI, -3.7 to -2.2 mm Hg), respectively. After adjusting for an outlier trial, the estimate decreased to -. 2.7 mm Hg (95% CI, -4.0 to -1.4 mm Hg) and -1.2 mm Hg (95% CI, -2.0 to -0.4 mm Hg), respectively. It is important to note that the trial for which adjustments were made was a study of black mild hypertensive patients. The active treatment group in this study experienced a BP drop of 39/17 mm Hg (Obel, 1989).

E. Africans and African-Americans

One trial conducted in Africa and several on subgroups in the United States are consistent with the idea that blacks may derive particular benefits from potassium supplementation (Matlou et al., 1986; Svetkey et al., 1987; Obel et al., 1989 & Brancati et al., 1996). Matlou et al. (1986) provided 65 mmol of potassium chloride daily to 32 hypertensive (153/101 mm Hg at baseline) African-American females during a 6-week placebo controlled crossover study. They experienced a BP drop of 7/3 mm Hg which was independent of the order of randomization and was significant for systolic BP ($P<0.01$) and diastolic BP ($P<0.05$) after 4 weeks. An analysis of the 95% confidence intervals in this study suggest that potassium supplementation did lower BP, but that the change was small.

Svetkey et al. (1987) provided a 120 mEq/day of orally administered potassium or a placebo to 101 adults with mild hypertension over an eight-week period. The decrease in BP of potassium treated group was significant at 6.4 +-13.7 (SD) systolic BP and 4.8 +- 8.3 (SD) diastolic BP. The results in the placebo group were insignificant. After adjusting for an unexpected higher BP in the controls at baseline, the BP still decreased 3.4/1.8 mm Hg more in the potassium treated group then the control participants. Even more significant than these results was a BP decrease by 19/13 mm Hg in five African

Americans taking potassium versus a 1/0 mm Hg increase in seven African Americans taking the placebo.

Obel (1989) did a similar study to the above double blind trial. This study was different in that the potassium supplement was 2,500 mg (64 mmol) per day, all subjects were Black (48 mild hypertensives) and the length of the study was 16-weeks. The participants on the potassium supplement experienced a steady significant decrease in BP during the trial. They had a net drop in BP of 10/8 mm Hg in four weeks, 31/13 mm Hg in eight weeks, 29/14 mm Hg in twelve weeks and 39/17 mm Hg in 16 weeks. The BP of the placebo participants did not change over the life of the study.

It is important to note that the baseline BPs of the controls and the potassium supplement users were quite high. Their average BP readings were 173/100 mm Hg and 175/100 mm Hg respectively. The patients on the potassium supplement experienced a significant increase in 24-h urinary potassium excretion. The post-treatment and baseline values were 102 versus 62 mmol/24-h urine ($p<0.001$), respectively.

To assess the effect of potassium repletion in hypokalemic hypertension, Kaplan and associates (1985) administered potassium chloride (60 mmol) or placebo tablets to 16 hypertensive patients (baseline BP of 131.5/102.4 mm Hg), each for six weeks, in a randomized double blind, crossover trial. The mean BP fell by an average of 5.5 mm Hg ($P=0.004$). Thirteen of the patients analyzed were black. This study demonstrated that potassium supplements could lower the BP in diuretic-induced hypokalemia. It further supports the idea that potassium depletion can increase BP levels. This fact has been demonstrated in healthy normotensive men (Krishna, 1989).

Brancati et al. (1996) did a randomized, double blind, placebo-controlled trial of 87 free-living African-Americans to test the effect of potassium supplements on a low-potassium diet. These healthy participants had systolic BP between 100-159 mm Hg and diastolic BP between 70 and 94 mm Hg. During the 21-day intervention period, all participants were provided a with a low potassium diet of 1,251.2 mg to 1,368.5 mg/day (32 to 35 mmol). The experimental group received a potassium supplement of 3,128 mg/day (80 mmol) while the controls received a placebo. Compared with the placebo group, the experimental participants experienced a net decline in systolic BP of 6.9 mm Hg (95% CI, -9.3 to -4.4 mm Hg; P<. 001) and a decline in diastolic BP of 2.5 mm Hg (95% CI, -4.3 to -0.8 mm Hg; P=. 004). These results are more impressive when we consider that the mean BP at baseline was only 125/78 mm Hg. The treatment effect increased progressively during the 21-days of intervention.

These study results underscore the important role of potassium intake in reducing BP in high-risk populations. This trial was the largest to test the role of potassium supplements in African Americans. It is the only study in which dietary potassium intake was fixed or an attempt was made to control dietary potassium in free-living individuals. The fixed level of potassium intake (32 to 32 mmol) is similar to the mean potassium intake for African Americans men (33 to 42 mmol) and women (30 to 32) aged 45 to 74 years in the general US population and corresponds to the lowest 10th percentile of daily potassium intake in all US men (30 to 39 mmol) and to the lowest 25th percentile in all US women (34 to 36 mmol) (Frisancho et al.1984 & Dietary Intake Source Data: NHS of USDHHS, 1983).

These daily potassium levels were calculated from 24-hour urine samples.

In contrast to the above findings on potassium supplementation and BP control, in phase 1 of the Trails of Hypertension Prevention (TOHP), a 60 mmol/d of potassium supplement produced no significant reduction in BP after 6 months in either 32 normotensive African-Americans participants (-0.4/-0.9 mm Hg) or their white counterparts (-0.0/-0.9 mm Hg) (Whelton PK, et al. 1995). It is important to note that the number of African Americans in the potassium arm of TOHP was small (n=13). A pooled analysis by Whelton et al. (1992) of six randomized trials in normotensive subjects revealed unimpressive reductions in BP. This analysis identified an overall mean reduction in systolic BP and diastolic BP of -0.8 mm Hg (95% CI, -1.9 to +0.3 mm Hg) and -0.7 mm Hg (95% CI, -1.6 to -0.7 mm Hg), respectively.

Brancati et al. (1996) gave several explanations for the difference between their finding and the TOHP study. The dietary potassium in their study was fixed at 32 to 35 mmol/d, while the participants in TOHP consumed their usual diet. It is very likely that these well educated health-conscious volunteers consumed diets higher in potassium rich foods (fresh fruits and vegetables) than their counterparts in the general population. It can be hypothesized that the blood pressure-lowering effect of potassium supplementation is greatest at low levels of dietary potassium intake. This hypothesis is supported by a number of trials that have demonstrated a BP lowering effect of potassium supplements in individuals with low potassium intake (Krishna et al., 1989; Lawton et al., 1990 & Kaplan et al., 1985).

In another potassium supplement trial, a BP drop of 14/10.5 mm Hg was achieved in 15 weeks (Siani et al., 1987). In this randomized double blind study, 18 experimental participants received 48 mmols of potassium daily while 19 controls received a placebo. All study participants were Italians and had mild hypertension (baseline BP 145/91 mm Hg). Compliance with the potassium prescription was confirmed by the significant increase in the mean 24-hour urinary potassium excretion in the actively treated group. The decrease in BP was gradual and significant at weeks three, six, twelve and fifteen. The mean baseline intake of potassium for all participants was low (59 mmol), while the mean sodium intake was high (200 mmol).

Current evidence suggests that a supplement of 1,877 mg (48 mmol) of potassium/day may be adequate for producing acceptable BP-lowering effects (Siani et al., 1987). The findings in a number of studies are consistent with the view that the higher the dietary sodium consumption, the more appreciable the BP-lowering effect of potassium (Siani et al., 1987; Obel, 1989 & Smith et al., 1985). Participants in the studies by Siani et al. (1989) and Obel (1989) consumed diets relatively high in salt intake and low in potassium.

The above studies by Obel (1989), Svetkey et al. (1987), Brancati et al. (1996) and Matlou et al. (1989) are consistent with the notion that blacks may derive particular benefit from potassium supplementation. This is apparently due to the fact that African-American communities are generally deficient in potassium intake and/or are inherently sensitive to potassium. These findings suggest that increased potassium intake might represent a safe and inexpensive and effective way to reduce blood pressure in African-

American adults who consume a diet low in potassium. These beneficial effects may be even greater in individuals on a diet relatively high in sodium intake.

In the clinical trial, Dietary Approach to Stop Hypertension (DASH), the researchers assessed the effects of dietary patterns on blood pressure in 459 adults (60% were African American) with diastolic BPs of 80 to 95 mm Hg and systolic BPs of less than 160 mm Hg (Appel, L.J. et al., 1997). In a three-week run-in period, all study participants were put on a diet low in vegetables, fruits, and dairy products with fat content typical of the average diet in the United States. They were then randomly assigned to receive for eight weeks the control diet, a diet rich in fruit and vegetables, or a diet rich in fruits, vegetables, and low-fat dairy products with reduced saturated and total fat. In this controlled feeding trial, sodium intake (approximately 3 grams/day) and body weight were maintained at constant levels in all three groups.

Baseline systolic and diastolic blood pressures were 131.3 mm Hg and 84.7 mm Hg, respectively. The combination diet reduced systolic and diastolic blood pressure by 5.5 and 3.0 mm Hg more, respectively, than the control diet (p=<0.001 for each). The fruit and vegetable diet reduced systolic blood pressure 2.8 mm Hg more (p=<0.001) and diastolic blood pressure by 1.1 mm Hg more (p=0.07) than the control diet. When the 133 subject with hypertension (140/90 mm Hg or higher) were compared, the combined diet reduced systolic and diastolic blood pressure by 11.4 and 5.5 mm Hg more, respectively, than the control diet (p=<0.001 for each). For the 326 study participants without hypertension, the corresponding reductions were 3.5 mm Hg (p=<0.001) and 2.11 (p=0.003) respectively.

This trial demonstrated that a high fruit and vegetable diet with low-fat dairy products and reduced total fat lowered blood pressure by 5.5/3.0 mm Hg more than a control diet. The decrease in blood pressure in minority subgroup was -6.8 mm Hg (-9.2 to -4.4; p=<0.001) systolic and -3.5 mm Hg (-5.2 to -1.8; p=<0.001) diastolic more in the cases than in the controls. There was a substantial increase in urinary potassium excretion for the fruit and vegetable group (1298 mg/24hr) and the combined group (1,500 mg/24hr) from the run-in period to the intervention phase. While the DASH study was not designed to identify the effective and ineffective components of the diet, sodium chloride, body weight and alcohol could not have accounted for the reduction in blood pressure.

Studies that address hypertension in the African-Americans, suggest that potassium supplementation is helpful in reducing BP in individuals with a low intake of dietary potassium and high intakes of dietary sodium. The results of the DASH study and a number of other clinical trials point to a BP lowering effect of nutrients in unique combinations or in specific food groups.

F. Nutrient Combinations and Controlled Trials

A randomized control study of 197 essential hypertensive patients was designed to determine the role of diet in controlling hypertension (Singh et al., 1990). Subjects were divided into two groups with each receiving diuretics. The study group's diet consisted of fish or other proteins to replace meat and eggs, and plenty of fruits such as bananas, oranges, guava, vegetables, such as spinach, tomatoes, cereals such as gram, peas, kidney beans, and nuts such as almonds and walnuts. This study was designed to significantly increase the content of potassium (K), magnesium (Mg), calcium (Ca), polyunsaturated fat, and complex carbohydrates compared to the normal diet for the control.

At the beginning of the study all subjects were comparable for mean serum levels of potassium, magnesium, sodium, calcium, age, sex, risk factors, mean BP and drug use. The mean baseline BP average was 152.2 mm Hg systolic and 99.8 mm Hg diastolic. After one year of follow-up subjects in the study group had significantly fewer patients with resistant HB (5 subjects) than in the control group (17 subjects). The mean BP for the intervention group and controls subjects were 148.22/90.2 mm Hg and 160/103 mm Hg respectively at study end point. The mean serum magnesium and potassium levels were significantly higher in the study group but non-significant when compared to initial levels. Complications were significantly lower in the study group (58) in comparison to the control group (100).

Drug and dietary advice was reinforced at regular 1-4 week intervals. Both groups were encouraged to maintain regular exercise programs, reduce or stop smoking and drinking of tea or coffee. It is possible that the combinations of nutrients in significant amounts in the study group were responsible for the reduction of BP and significantly lower complications. However, we cannot for sure say which nutrients were responsible for the BP lowering effects. Subjects being human may have varied from maintaining their usual lifestyle habits and dietary dairies. Perhaps even stronger results could have been achieved. Nevertheless, this study demonstrates that longer-term complex dietary programs can positively impact on hypertension and its complications.

An eight week controlled trial to treat hypertensive patients demonstrated that the dietary combination approach is effective in treating hypertensive patients on medication (Little et al., 1990). One hundred and ninety three essential hypertensive patients were sequentially assigned to one of five groups; controls with no change in diet, high fiber diet, low sodium diet, low fat diet or a combination diet of low sodium, low fat, high fiber = 40-45 g, 40-50 mmol of sodium and 23-25% calories as fat per day.

The low fat group showed a small but significant decrease in diastolic BP and weight. The combination group showed a highly significant decrease in BP. None of the other groups showed a significant effect on BP levels. Compliance as rated by the subjects was good to very good. Most people rated the diets as palatable. The worst ratings were among the combination diet. Even though these ratings improved along the life of the study, we cannot be sure that the subjects were totally honest in their evaluation. The result may have been even stronger if compliance was higher. Since no biochemical tests were employed to validate dietary intake, we have to rely on subjective reports, compliance assessments by dietitians and food frequency interviews at three times during the study.

A more tightly controlled study identified a significant BP lowering effect in a low sodium (8 mmol), high potassium (6 mmol) and high magnesium (1 mmol) mineral salt combination (Geleijnse et al., 1994). This randomized double blind placebo controlled trial of 100 untreated mild hypertensives demonstrated a fall in systolic BP of 7.6 mm Hg and a diastolic fall in BP of 3.3 mm Hg in the mineral salt group when compared to the control group over a twenty four week period. Through this mineral preparation, sodium intake was reduced by 38 mmol, potassium intake was raised by 18 mmol and magnesium intake was raised by 7 mmols.

The actively treated group received this salt preparation and foods prepared with the mineral salt, while the control group received regular salt and foods prepared with regular salt. Twenty-four hour sodium and potassium excretions were significantly greater in the mineral salt group when compared to the control group. Foods were rated equally by the two groups except for bread and table salt which were considered significantly less salty by more people in the mineral salt group. The diaries, food records and 24-hour excretion rates for sodium and potassium indicated good adherence to the protocol in both groups.

The results of this study suggest an additive effect was produced by the combination of increased potassium and magnesium intake and decreased sodium intake. Previous studies predicted smaller drops in BP with similar changes in urinary potassium excretion without magnesium added to the supplement (Elliott et al., 1989 & Cappuccio et al., 1991). This study demonstrated that replacing common table salt with a low sodium, high potassium, high magnesium salt, we can offer a valuable non-pharmacological approach to lowering BP in older people with mild to moderate hypertension.

A whole food approach to BP control that increases dietary intakes of potassium and magnesium rich foods might be a more effective alternative to a mineral salt combination. Such an approach might duplicate these findings, or better still, result in more significant drops in BP due to the presence of other nutrients in these foods. The following studies address the effects of potassium and or magnesium rich foods and BP levels in hypertensive patients.

Fifty-four well-controlled hypertensive patients were randomly assigned to one of two groups and were given dietary advice designed to selectively increase potassium rich foods in group 1 or keeping the customary diet unchanged in group 2 (Siani et al., 1991). During the 1-year follow-up period the BP was reduced in a step-wise fashion, provided the BP remained below 160/95 mm Hg. Forty-seven participants completed the 1-year follow-up. To minimize the placebo effect, patients were unaware of two distinct groups and were given identical care. These groups were similar in most ways including the dropout rate due poor adherence to the study protocol.

A list of equivalent potassium rations of locally available legumes, fruit and vegetables containing from 391 to 496 mg of potassium (10 to 12 mmol) was provided for the study group. The participants were advised to consume three to six rations per day without major changes in their whole dietary pattern. Potassium intake was checked monthly by referring to 3-day records and by measuring 24-hour urinary excretion.

By the end of the study the only significant difference between the two groups was the intake of dietary potassium consumed by the cases. Drug use in group 1 and group 2 was 24% and 60% respectively by the end of the study when compared with baseline values. By the end of the study BP could be controlled with 50% less medication in 81% of the patients in group 1 compared with 29% of patients in the control group. At the end of the 1-year follow-up 38% of group 1 had well controlled BP without any drug therapy compared with 9% for the control group. It was determined that this BP lowering effect could not be attributed to dietary fiber, calcium, calorie intake, weight level, a decrease in alcohol consumption, a change in P/S ratio, sodium intake, or differences between the two groups. The researchers concluded that the 50% increase in the average potassium intake was responsible for most if not all the decrease in drug consumption achieved in the group with the high potassium diet. Magnesium intake was not analyzed in this study.

Two randomized single-blind trials by Singh and associates (1992 & 1993) have provided evidence of the BP lowering effects of guava fruit. In the first study, 120 patients with hypertension (>150/95 mm Hg) were divided between controls (group B) and experimental participants (group A). Group A was administered 0.5 to 1.0 kg/day of guava fruit in a foods-to-eat approach rather than foods-to-restrict. It was to be eaten preferably before meals to displace foods rich in saturated fat and cholesterol. Group B was asked to maintain the usual intake throughout the study. Both groups were asked to maintain usual physical activity, salt intake, and body weight. Mean baseline values for both groups were similar for body weight, P/S ratio, BPs, fruit, fiber, sodium, potassium, alcohol and intakes of carbohydrates, protein, cholesterol and fats. All patients were given aluminum hydroxide tablets to minimize the placebo effect of a high guava fruit diet. Adherence to guava consumption was assessed by questionnaires and weighing of guava intake at 12 weeks of follow-up by 24-hour recall.

At the end of the 12-week intervention, there was a significant net decrease in BP (9.0/8.0 mm Hg) in group A when compared with group B. There was also a significant net decrease in serum total cholesterol (9.9%) and triglycerides (7.7%) and a significant net increase in high-density lipoprotein cholesterol (8.0%). Significant changes were also seen in levels of vitamin C, sodium, potassium, grams of guava intake, and sodium to potassium ratio, and P/S ratio between group A and group B. The significant reduction in BP may have occurred because of an increased intake of dietary potassium and a decreased sodium/potassium ratio in the diet. However, it is not absolutely clear which component of the diet, or guava fruit was responsible for the change in BP since the incorporation of guava into the diet led to self-initiated changes in dietary fat intake as well as increased consumption of soluble fiber, potassium and vitamin C.

Based on the evidence of a number of studies reviewed in this paper, it is likely that potassium played a major part in the reduced BP in group A participants (Obel, 1989, Svetkey et al., 1987, Brancati et al., 1996 & Matlou et al., 1989). The mean baseline intake for potassium in both groups (937 mg) of these Indian patients was lower than the mean potassium intake for African-Americans (1,251-1369 mg) (Brancati et al. 1996). Individuals with low potassium intakes respond with greater changes in BP when potassium is added to the diet. The intervention group received significantly higher amounts of guava (405 vs. 165 g/day) than the control group. The mean potassium difference for group A (final-baseline) was 415 mg, while the mean potassium difference for group B (final -baseline) was 95 mg.

A guava intake of 0.5-1.0 kg/day (group A) provided from 455 to 910 mg of potassium per day, and 114 to 228 mg of magnesium per day. Although the guava intake provided good amounts of magnesium to the diets of the group A, the changes in serum level of magnesium were insignificant for this group after 12 weeks of intervention. It is important to note however, that the significant drop in BP was achieved with a potassium increase that was far less than the potassium levels in the potassium supplementation trials examined in this literature review. This difference could be due in part to an additive effect produced by a combination of potassium and other nutrients present in the guava fruit. The data from the study by Geleijnse et al. (1994) provides us with reasons to suggest that sodium, potassium and magnesium are all involved.

The second trial by Singh et al. (1993), while using the same design as their first guava fruit study, produced very similar results. In this clinical trial, 72 patients received the guava diet, while 73 patients ate their usual diet. After a four-week follow-up, the actively treated group experienced a net decrease in BP of 7.5/8.5mm Hg when compared with a control group. There were also significant decreases in serum total cholesterol (7.9%) and triglycerides (7.0%). There was also an insignificant increase in HDL-cholesterol (4.6%) in the actively treated group when compared to controls.

These two studies suggest that an increased consumption of guava fruit can cause a significant reduction in BP. This is most likely due to its higher potassium content. The magnesium content of the guava fruit may also have had an impact on BP reduction. Further, like the previous trials on nutrient combinations, these two studies demonstrate that the prevalence of hypertension can be reduced safely by utilizing whole food items that are rich in potassium and perhaps magnesium. They also demonstrated that major changes in dietary habits are not necessary to produce significant reductions in BP.

G. Conclusions

In conclusion, there is now convincing evidence from epidemiological studies and randomized controlled trials that complex vegetarian diets reduce systemic blood pressure in both normotensive and hypertensive subjects. This effect is independent of dietary sodium and weight loss, but is additive to the effects of weight reduction. Specific combinations of foods rich in particular nutrients may be responsible for the anti-hypertensive effects of vegetarian diets – that is, foods high in potassium and magnesium. Resolution of these questions may lead to a more widespread adoption of dietary habits that will result in the prevalence of hypertension in the U.S. that is seen in people groups who subsist on a largely vegetarian diet.

H. Discussion and Implications of Literature Review for Current Study

This literature review supports a focus on BP research that looks at selected vegetarian foods containing high quantities of specific nutrients that are known to lower BP. Such an intervention may provide us with a dietary approach to BP control that is far superior to a focus on specific nutrients in isolation.

With this scientific background, a dietary intervention study on blood pressure control in African Americans was designed and implemented. Since African Americans as a group consumes low potassium high sodium diets and are disproportionally affected by hypertension than other groups, a positive and simple dietary approach to BP control might prove beneficial.

CHAPTER 3

METHODOLOGY

A. Research Purpose and Design

This randomized control study compared the effects of high intakes of bananas, orange juice and raisins on systemic BP in African-American men and women (20 to 65 years old) with systolic BPs between 130-159 mm Hg and/or diastolic BPs between 85-99 mm Hg over a six week period. The study sample consisted of 36 healthy free-living adult members from participating churches in San Bernardino California and 2 African Americans from Loma Linda California.

According to research design, study eligibility was established during a three week screening phase. During the six-week intervention period, the control group continued their pre-study dietary and lifestyle practices. The experimental group was encouraged to increase their intake of raisins, orange juice and raisins that were provided during the six-week intervention. The study endpoints were the changes in BP from baseline to week three and then to week six of the intervention. The pre-screening, screening and intervention phases of this study proceeded as follows:

1. 2 Weeks Before First Screening Date

Screening location (churches) and dates and time for screening were established by this week. Most study team members were recruited by this time period as well. They included health professionals from participating churches, Loma Linda University and Loma Linda Community. Permission to use the church members as study participants was obtained from the church pastors of Temple Missionary Baptist Church (TMBC), Ecclesia Christian Fellowship and SanBernardino Christian Centre. See Appendix A.

During this week, the specific roles and meeting times for study team members was determined. At theses meetings team members addressed protocols for screening and the study intervention activities which included BP monitoring, food distribution, record keeping, urine collection, food records and height and weight measurements.

2. 1 Week Before First Screening Date

Prior to or during this pre-screening period, BP equipment, height and weight instruments, health appraisal questionnaires, food supplies and materials needed for urinary analysis were secured. Financial arrangement to cover the equipment, screening activities and food supplies for the intervention was also addressed.

Study team members from Loma Linda University went through an orientation process on BP procedures and activities that were during the screening and intervention phases of this research project. The guidelines for both routine and emergency medical referral were confirmed during this time as well. Each team member was provided with a written summary of the protocols and/or responsibilities they need to follow. Some team members were involved in BP screening, while others entered data collected into the software programs. See Appendix B. for a list of BP protocols.

3. Week of First Screening Date

The pastor and members of the church Nursing Guild at TMBC played an active part in the screening process. Each week starting from this date, the church congregation was screened for study participants that met our eligibility criteria. The screening took place on Sunday mornings between the first (10:00 to 11:00 AM) and second service, as well as after the second service (l: 00 to 2:00 PM) of that same day for the first week of screening. The church members that qualify during this first screening date returned for the second and third screening dates on the following two Sundays, providing they meet the study eligibility requirements each week. From the second week on, all screening activities at TMBC took place between the first and second service. These multiple BP readings enabled us to establish the fact that all study participants had BP levels between high normal and mild-hypertension.

This weekly screening was important for several other reasons. The program focus for each Sunday service of the month attracted a different audience (Communion, Youth, Young Adult and Golden Agers). Hence, we encounter new groups of people each Sunday. Secondly, we were able to determine ahead of the time that we needed to screen additional study participants from Ecclesia Christian Fellowship and San Bernardino Christian Center.

During the church services, the pastor made an announcement regarding the study and encouraged the members to get their BP checked after the service. A study team member followed the pastor by giving more details on the study and listed several major criteria for being a study participant. The BP screening process was also explained. Church members that agree to get their BP checked were directed to the church multi-purpose room following the church service for this screening activity.

Study team members at the check-in area directed the church members to the tables designated for BP monitoring. While the church members were being seated in the screening area, study team members provided information on the next step to be taken for those persons with BP readings that qualify them for further screening activities. This instruction included among other topics, the need for additional BP readings, completing a health questionnaire and getting height and weight measurements. A number of church members filled out forms while waiting to get their BP taken. We averaged between four and eight BP operators to screen this population. A five-minute rest period preceded BP measurements.

All individuals that agreed to try out for the study completed a study eligibility form and a handout on informed consent. See Appendix C & D. Study team members signed as witnesses to the informed consent guidelines for the church members that agreed to try out for the dietary intervention. All church members with BP levels that were within the range for this study, and who agreed to become study participants received all additional BP checks from the Clinical Life-Sign Automatic BP monitoring device. These BP checks included two readings with no less than two minutes apart. If the results of the two BP readings varied by more than 5 mm Hg, a third BP reading was taken no earlier than 30 seconds later. These BP readings were then averaged. Markings on the BP cuff were used to determine whether a regular or large cuff size was used for the study subjects.

These participants took their screening forms to the height and weight station. After getting his or her height and weight measured, each participant went to the checkout station. Team members at the checkout area double-checked the screening forms to ensure that all information was filled out correctly.

Persons that qualified during the first screening period were instructed to return on the following Sunday for the second BP screening between the first and second service.

Non-qualifying individuals (normal BP readings) were directed from the screening area, while all persons with high BP readings (non-qualifiers) remained seated for an additional two minutes before getting a second BP reading. All non-qualifying individual with high BP readings were directed to the referral station for counseling and referral to a physician or clinic for follow-up care if needed. A standard letter was provided for the participant's health care provider which included the client's BP readings, information regarding the research study and a request to follow-up with the individual. See Appendix E for the BP referral guidelines and Appendix F for the Physician referral letter. See Appendix G for flow chart of first screening exercise.

4. Week of Second Screening Date

The screening activities of the first week were repeated during the second week of screening for first time individuals. Individuals screened for the second time picked up their BP forms at the check-in area before going to the BP measurement area. All individuals that qualify during the second week of screening received instruction on collecting a 24-hour urine sample. (See Appendix H.) Study team members provided these screened individuals with containers to collect the urine samples and informed them that they would be randomized into separate groups on the following week after a third BP screening.

Study team members went over the Health Habits and History Questionnaire (HHHQ) and answer any questions regarding its completion to the screened subjects.

The National Cancer Institute produced this questionnaire. (See Appendix I.) The questionnaire took about 30 minutes to complete. Pages eight and nine were omitted from the questionnaire. Most of this information was not relevant to this study. See Appendix J for the flow chart of the second week of screening.

At the end of week two, it was determined that a second church needed to be screened to increase the number in our study population. Arrangements were made to begin screening at San Bernardino Christian Centre for additional study participants on the following week.

5. Third Screening Date / Baseline / First Week of Intervention

The screening activities of the first and second week were repeated during the third week of screening for all first and second time individuals at TMBC between the first and second service. Individuals screened for the third time dropped of their urine samples and pick up their BP forms at the check-in area before going to the BP measurement area. The mean BP readings for the three screening periods were tabulated to establish a baseline BP reading.

These individuals were randomized into two groups, experimental and control. To do this, we marked and folded enough slips of paper for each study qualifier with half marked with the letter A and the other half marked with the letter B. After putting these papers in a bag, we asked each study participant to draw out one slip of paper. The study participants that pick out the papers marked with the letter A became the experimental group while the study participants that pick out the papers marked with the letter B became the control group.

Group B was instructed to continue their pre-study dietary and lifestyle practices for six weeks. At the end of the six-week intervention the controls were given the same food items provided for the experimental group. Since the control group was not blinded to the dietary intervention, the fruits were provided for them to: (1) reduce the likelihood of resentment for being left out, (2) decrease the temptation to increase fruit and vegetable consumption during the intervention phase, and (3) show appreciation for participating in the study.

Group B participants were given a food diary on which to record their daily intakes of fruit, vegetables eggs and other foods. See Appendix K Group team members informed them of the dates for mid-study and week six BP readings. They also received instruction on when to bring in their food diaries and a final 24-hour urine collection.

Group A participants were given instruction on how to fill out a fruit and vegetable diary which they used for the duration of the study. (See Appendix L.) Study team members explained the importance of increasing their daily intake of fruit and vegetables and maintaining all other dietary and lifestyle practices during the length of the intervention. The goal was to increase daily intakes of potassium to levels that have been demonstrated to lower BP in hypertensive individuals. We also hoped to increase their dietary intake of magnesium.

The weekly supply of bananas, orange juice and raisins provided six or more servings per day from the fruit group. This amounted to three 6 oz cups of orange juice, 3 medium bananas (4 oz), and one to two 1 ½ oz pack of raisins per day. These foods alone provided from 2970 to 3,293 mg of potassium and 187 to 202 mg of magnesium per day. The daily values for potassium and magnesium are 3,500 mg and 400 mg respectively. In addition to this fruit intake, the study participants were encouraged to consume from three to five serving of vegetables per day.

Group A participants picked up a week's supply of fruit every Sunday for six weeks. They were informed of the pick up times for fruit supplements and the need to make other arrangements to receive the fruit if they were unable to come at the appointed time. The intervention for Group A participants began after all the cases were selected for the intervention. See Appendix M for the screening flow chart for week three.

The screening activities began at San Bernardino Christian Centre. Church members at this facility were screened after the first and second services using the same format as at TMBC. After the first week of BP screening, most of these church members were followed up at the mid-week church service. On the following week, the study screening activities began at Eccletia Christian Fellowship. All screening and follow-up activities at this church took place after the mid-day service.

6. Week One to Week Three of Intervention

Group A participants picked up a weekly supply of bananas, orange juice and raisins from a designated area in their respective church facility. Study team members coordinate the distribution of these food items to the participants. The experimental group was encouraged to consume the daily intake goals for fruits and vegetables as recorded on their food diaries. Each week they handed in a fruit and vegetable diary. At week six, all group A participants received a mid-study blood pressure check.

Group B participants submitted three weeks of food diaries at mid-study. They also received a mid-study blood pressure check.

7. Week Four to Week Six of Intervention

Experimental participants picked up weekly supplies of bananas, orange juice and raisins from a designated area in their respective church facility. Team members coordinated the distribution of these food items as well as receiving their weekly fruit and vegetable diaries. All individuals who failed to show up for their food supplies were followed up on.

At the end of the sixth week, all study participants filled out a second food frequency questionnaire, got two final BP readings and collected a second 24-hour urine sample. The study participants were told to complete the dietary questionnaire with a focus on their dietary habits during the previous six weeks. It covered the activities involved with this research project.

B. Data Analysis

1. Confounding Factors

The potential confounding factors such as changes in body weight, alcohol intake, smoking, physical activity, baseline blood pressure and dietary factors derived from analysis, were adjusted for during data analysis using Multi variant Analysis of variance (and covariance). The study participants were requested to record any changes from the study protocol. The questionnaire included a number of these confounding factors.

Adherence to the dietary intervention was assessed by self-reports of fruit and vegetable consumption and biochemical measurements. Based on 24-hour urinary excretion of sodium and potassium, individual adherence was assessed. Group adherence to the high fruit diet was determined by the changes in urinary potassium excretion levels for each group from baseline to end of study.

2. Measurements

Blood pressure measurements were taken with the LifeSign Clinical Blood Pressure Monitor. This automatic blood pressure device was used with the subjects in the seated position, using the right arm, 1 hour after the last meal and 30 minutes after smoking or consumption of a caffeinated beverage. The first BP reading was taken after a 5-minute rest. The second BP reading was taken a minimum of 2 minutes latter. One automatic BP monitor was used for all study subjects.

Laboratory measurements were assessed at the clinical laboratory at the Nutrition Department at Loma Linda University School of Public Health. The urinary excretion values were analyzed on the Varian Atomic Absorption Spectrophotometer AA-475 series. Nutritional assessment and height and weight of participants will be assessed using standard techniques and instrumentation. The Scale-Tronix electronic weight scale was used in this study.

3. Safety Considerations

If BP rose above 170 mm Hg systolic or 105 mm Hg diastolic at any point, the pressure was rechecked at a second visit within 1 week. If the BP remains above this level, a referral was made to a physician for further evaluation and treatment.

A systolic BP higher than 180 mm Hg or a diastolic BP higher than 110 mm Hg at any single visit lead to an immediate referral.

Subjects who required medication were excluded from further participation in the study.

4. Sample Size Estimate and Analysis

The projected sample size was 80 subjects in each group. This sample size would allow for a 20% dropout following randomization and the anticipation of several confounding factors. The actual study sample size included 19 subject in each group. It was determined that a sample size of 20 subjects in each group was sufficient to detect a diastolic BP fall of 5 mm Hg with a power of 90% at an alpha level of .05 (Barko et al., 1988). These calculations included the assumption that no confounding factors would be identified.

Given the power, alpha level, and the anticipated mean difference in BP between the two groups, the sample size calculation was determined using empirical data from the Trials of Hypertension Prevention which suggested a standard deviation of 5 mm Hg based on measurements recorded over 3 days (Satterfield et al. 1991). A two-sample Student□s T- Test was be used to analyze these results. Multi variant and Univariate Analysis of variance (and covariance) was also used.

CHAPTER 4

RESULTS

A. Introduction

Thirty-eight individuals underwent random assignment, 19 to the fruit and vegetable group and 19 to the control group. All 38 participants completed the six-week study. The age range of the participants was 24 to 65 years, with a mean age of 44. Thirty study participants (79%) were female and 8 (21%) were male. According to body mass index calculations (kg/m²), 24 (63.15%) participants were obese (8 males & 16 females), 11 (28.94%) females were overweight, and another 3 (7.89%) females were at the recommended weight level. Baseline differences in age, smoking status, alcohol intake, activity level and weight status were all non-significant between the two groups (Table 1).

Using the criteria of the Joint National Committee on Detection, Evaluation, and Treatment of High Blood Pressure, 24 (63.15%) participants had systolic blood pressure readings in the high normal range (130 to 139 mm Hg), and 7 (18.4%) had systolic blood pressure readings in the mild hypertension range (140 to 159 mm Hg). Fifteen (39.47%) participants had diastolic blood pressure readings in the high normal range (85 to 89 mm Hg), and 18 (47.3%) had diastolic blood pressure readings in the mild hypertension range (90 to 99 mm Hg). At baseline, the intervention and control groups were not significantly different in their mean blood pressure (134.66/90.68 Vs 136/88.79 mm Hg) levels (Table 2).

Table 1. Baseline Characteristics of 38 African Americans by Treatment Assignment *

Characteristic	Control (N=19)**	Fruit and Vegetable (N=19)**	P-value
Age in years	41.16±7.77	46.32±11.11	.106
Female (%)	14 (36.8)	16 (42.1)	
Male (%)	5 (13)	3 (7.9)	
Present smoker	1.95±.23	1.95±.23	1.00
Alcohol beverages, No./wk	1.84±3.17	.74±2.21	.220
Exercise days/wk	1.37±.76	.53±1.22	.635
Body mass index (kg/m^2)	31.71±4.70	32.22±7.48	.803
Obese	13±2.86 (n=13)	11±6.82 (n=11)	.301
Overweight	26.81±1.73 (n=5)	27.91±6 (n=6)	.276
Ideal weight	22.67±0 (n=1)	21.69±.55 (n=2)	.385

* All variables are shown as mean±SD unless otherwise indicated.

** All study participants are represented in each characteristic.

Table 2. Baseline Blood Pressure Characteristics of 38 African Americans by Treatment Assignment *

Characteristic	Control (N=19)**	Fruit and Vegetable (N=19)**	P-value
Blood pressure, mm Hg			
Systolic	134.66±7.12	136.03±8.31	.588
Diastolic	90.72±6.21	88.79±5.45	.318
Systolic (high normal)	133.88±2.38 (n=10)	134.14±2.98 (n=14)	.818
mild hypertension	145.90±4.00 (n=4)	151.78±7.33 (n=3)	.226
Diastolic (high normal)	86.83±2.07 (n=6)	86.36±1.55 (n=9)	.628
Mild hypertension	95.01±3.08 (n=11)	94.85±3.08 (n=7)	.918

* All variables are shown as mean±SD unless otherwise indicated.

** All study participants are represented in each characteristic unless otherwise indicated.

The nutritional data for individuals in the control and intervention group at baseline were very similar. They were not significantly different in daily intake of bananas (.36 vs. .52), orange juice (.41 vs. .47), raisins (.00 vs. .00), fruit (1.13 vs. 1.53), and vegetables (2.18 Vs 2.42) (Table 3.). Specific nutrient comparisons between the intervention group and the control group were non-significant for baseline values of dietary potassium (3312.85 vs. 3404.16 mg), magnesium (296.10 Vs 332.16 mg), calcium (995.85 vs. 971.57 mg) and sodium (4043.56 vs. 4142.65 mg) (Table 4.). The controls and the fruit and vegetable groups were also not significantly different for 24-hr. urinary excretion levels of potassium (1469.66 vs. 1671.78 mg), sodium (3276.21 vs. 3115.21 mg), calcium (115 vs. 79.40 mg) and magnesium (68.44 vs. 67.10 mg) at baseline (Table 5).

Table 3. Baseline Fruit and Vegetable Intake of 38 African Americans by Treatment Assignment *

Characteristic	Control (N=19)	Fruit and Vegetable (N=19)	P-value
Servings/day			
Bananas (medium)	.36±.52	.26±.24	.433
Orange juice (6 oz.)	.41±.47	.70±.55	.100
Raisins (1 ½ oz)	.	.	.
Fruit (1 piece, ½ cup)	1.13±.77	1.53±.93	.154
Vegetable (½ cup)	2.18±1.04	2.42±1.22	.526

*All variables are shown as mean±SD

Table 4. Baseline Nutrient Intake of 38 African Americans by Treatment Assignment *

Characteristic	Control (N=19)	Fruit and Vegetable (N=19)	P-value
Dietary nutrients			
Potassium (mg)	3312.84±1297.87	3404±1684.60	.853
Magnesium (mg)	296.10±118.14	332.16±156.06	.427
Calcium (mg)	995.85±642.28	971.57±595.85	.905
Sodium (mg)	4043.55±2482.16	4142.64±2030.13	.894

*All variables are shown as mean±SD

Table 5. Baseline 24-hr. Urinary Characteristics of 38 African Americans by Treatment Assignment *

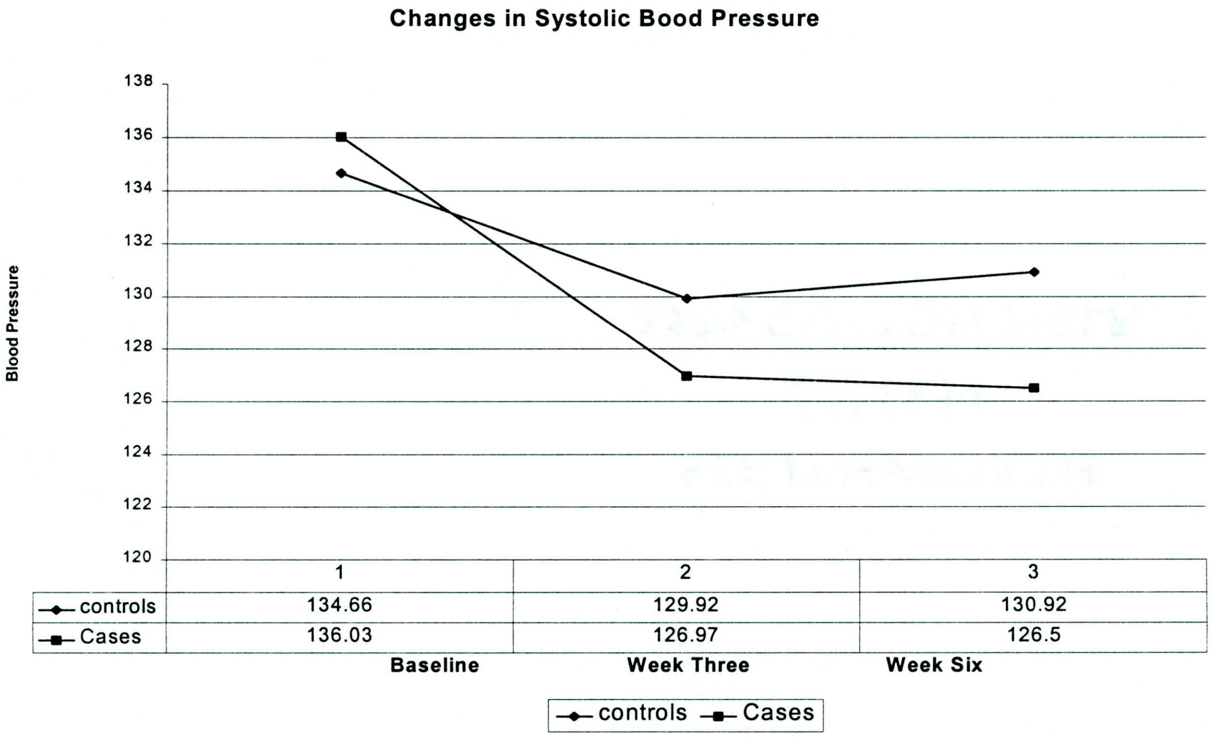
Characteristic	Control (N=19)	Fruit and Vegetable (N=19)	P-value
24 hr. urinary values,			
Potassium	1469.67±726.91	1671.79±678.82	.382
Sodium	3276.21±1886.75	3115.22±1679.43	.783
Calcium	115.58±85.72	79.40±61.43	.143
Magnesium	68.44±24.77	67.10±33.33	.889

* All variables are shown as mean±SD

B. Blood Pressure Results

Changes in blood pressure readings from baseline to week three and week six of the intervention are illustrated in Figures 1 to 4. This data has also been summarized in Table 6. Compared to the control group, the high fruit group experienced a statistically significant net decline in systolic blood pressure of 4.32 mm Hg (95% confidence interval, .18 to 8.45 mm Hg; p=.041) after three weeks and 5.79 mm Hg (95% confidence interval, 1.53 to 10.05 mm Hg; p=.009) after six weeks (Figure 1). With regard to changes in diastolic blood pressure, the intervention group experienced a non-significant net decline in diastolic blood pressure of 3.53 mm Hg (95% confidence interval, .33 to 7.39 mm Hg; p=.07) after three weeks and a statistically significant decline in diastolic blood pressure of 3.76 mm Hg (95% confidence interval, .05 to 7.46 mm Hg; p=.047) after six weeks (Figure 2).

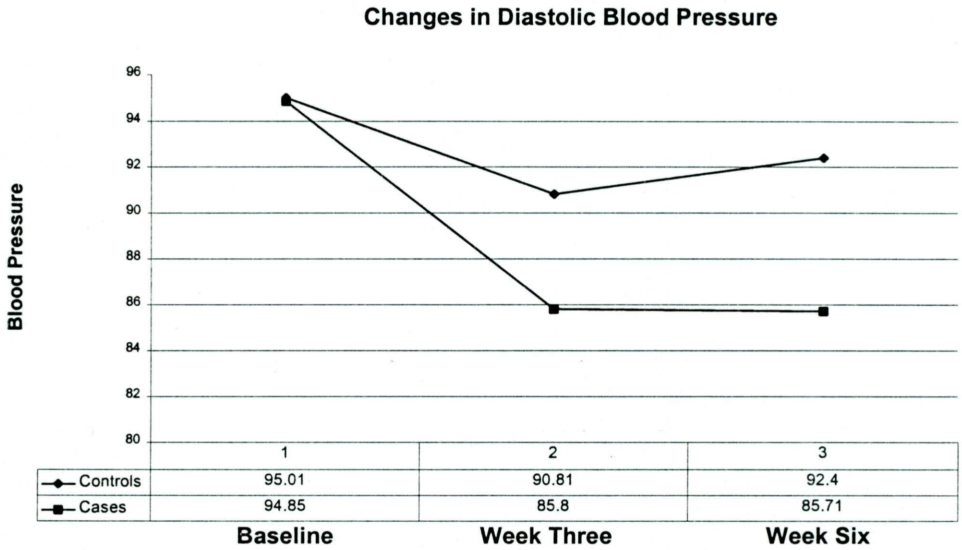
Figure 1. Changes In Systolic Blood Pressure During Six Week Intervention



	1	2	3
controls	134.66	129.92	130.92
Cases	136.03	126.97	126.5
	Baseline	Week Three	Week Six

Cases SBP 4.32 mmHg p=.041 5.79 mmHg p=.009

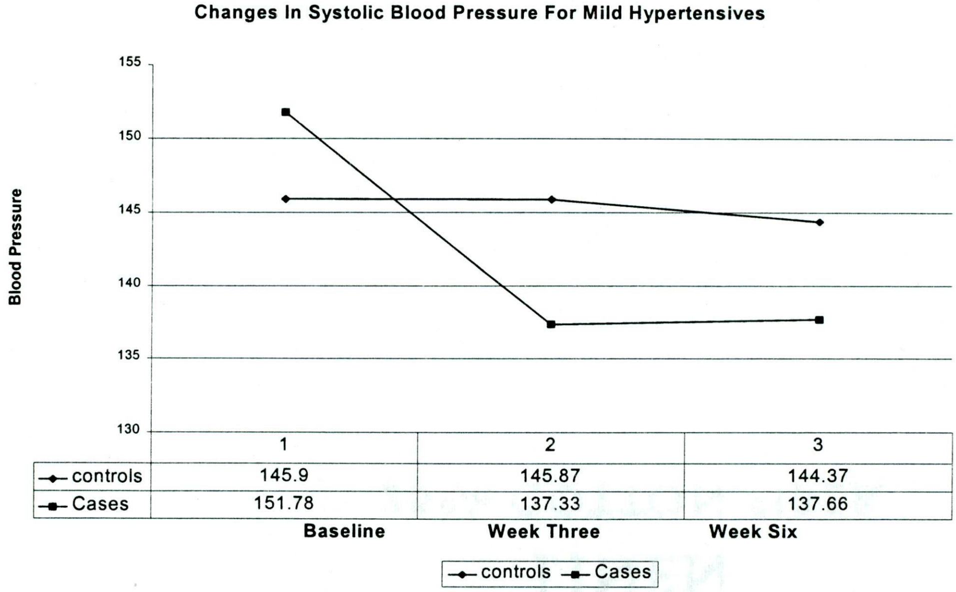
Figure 2. Changes In Diastolic Blood Pressure During Six Week Intervention



Cases DBP 3.53 mmHg p=.07 3.76 mmHg p=.047

Analysis was also conducted comparing the control and intervention group to explore the effects of the intervention on blood pressure in study participants who had mild hypertension. Compared with the control group in this blood pressure category, the high fruit group experienced a statistically significant mean difference in systolic blood pressure of 14.42 mm Hg (95% confidence interval, 3.46 to 25.37 mm Hg; p=.02) after three weeks and a non-significant mean difference of 12.6 mm Hg (95% confidence interval, 5.32 to 30.50 mm Hg; p=.131) after six weeks (Figure 3).

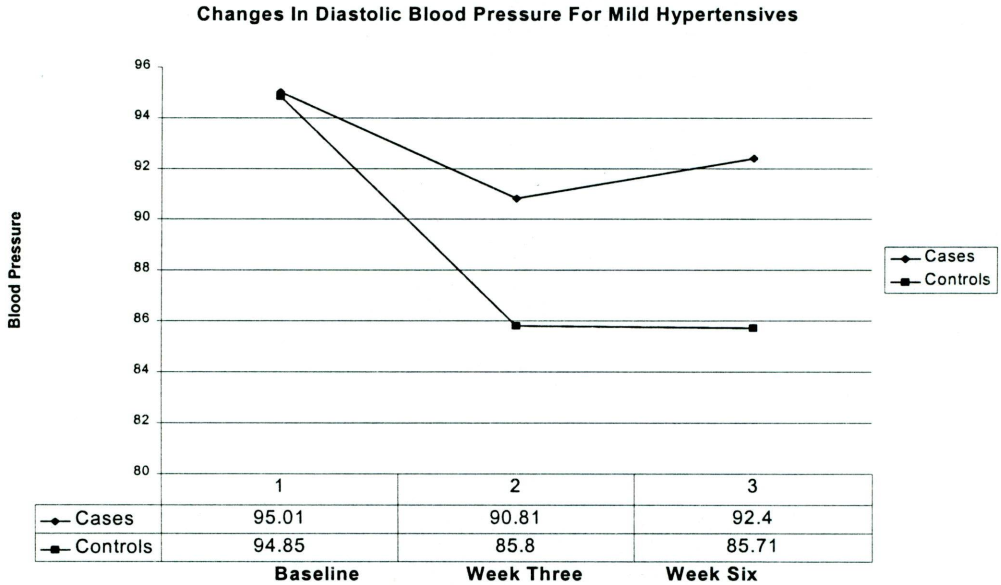
Figure 3. Changes In Systolic Blood Pressure For Mild Hypertensive Participants During Six Week Intervention



	1 (Baseline)	2 (Week Three)	3 (Week Six)
controls	145.9	145.87	144.37
Cases	151.78	137.33	137.66

Cases SBP 14.42 mmHg p=.02 12.6 mmHg p=.131

Figure 4. Changes In Diastolic Blood Pressure For Mild Hypertensive Participants During Six Week Intervention



	1 (Baseline)	2 (Week Three)	3 (Week Six)
Cases	95.01	90.81	92.4
Controls	94.85	85.8	85.71

Cases DBP 3.94 mmHg p=.171 6.53 mmHg p=.014

Using these same comparisons for diastolic blood pressure results, the intervention group experienced a non-significant mean difference in blood pressure after three weeks of 3.94 mm Hg (95% confidence interval, 1.87 to 9.76 mm Hg; p=.171) and a statistically significant mean difference in blood pressure of 6.53 mm Hg (95% confidence interval, 1.5 to 11.56 mm Hg; p=.014) after week six (figure 4). These results show the largest decrease in blood pressure for the high fruit group with mild hypertension.

When singling out the study participants with high normal blood pressure, significant drops in blood pressure were also identified (Table 6) Compared to the control group in this category, the high fruit group had a mean difference in systolic blood pressure of 4.34 mm Hg (95% confidence interval, .04 to 8.64 mm Hg; p=.048) and a non-significant mean difference in diastolic blood pressure of 1.95 mm Hg (95% confidence interval, 3.96 to 7.86 mm Hg; p=.497) after the six week intervention. All other comparisons for high normal BP reading were non-significant.

Table 6. Change (Week Three and Week Six Follow-up Minus Baseline) in Blood Pressure Characteristics During Intervention in 38 African Americans by Treatment Assignment*

Characteristic	Mean±SD Control (n= 19) **	Mean±SD Cases (n=19) **	Mean Difference	P-value
Week three BP results				
Blood pressure, mm Hg				
Systolic (all)	-4.70±6.40	-9.06±6.15	4.32 (.18 to 8.45)	.041
Diastolic (all)	-2.69±5.34	-6.22±6.35	3.53 (-.33 to 7.39)	.072
Systolic				
high normal	-6.00±6.31 (n=15)	-8.00±5.71(n=16)	2.05 (-2.36 to 6.47)	.350
mild hypertension	.03±4.77 (n=4)	-14.45±6.60 (n=3)	14.42 (3.46 to 25.37)	.020
Diastolic				
high normal	-.63±4.15 (n=8)	-4.5±7.02 (n=12)	3.94 (-1.87 to 9.76)	.171
mild hypertension	4.19±5.78 (n=11)	-9.00±4.01 (n=7)	4.85 (-.46 to10.18)	.071
Week six BP results				
Systolic (all)	-3.74±6.38	-9.53±6.56	5.79 (1.53 to10.05)	.009
Diastolic (all)	-2.85±5.52	-6.61±5.73	3.76 (.05 to7.46)	.047
Systolic				
high normal	-4.33±5.78 (n=15)	-8.68±5.90 (n=16)	4.34 (.04 to 8.64)	.048
mild hypertension	-1.53±8.93 (n=4)	14.12±9.40 (n=3)	12.60 (-5.32 to 30.50)	.131
Diastolic				
high normal	-3.19±5.73 (n=8)	-5.14±6.42 (n=12)	1.95 (-3.96 to 7.86)	.497
mild hypertension	-2.60±5.63 (n=11)	-9.13±3.35 (n=7)	6.53 (1.50 to 11.56)	.014

* All variables are shown as mean±SD unless otherwise indicated.

** All study participants are represented in each characteristic unless otherwise indicated. All P-values include adjustments for possible confounders in the MANOVA model

C. Adjusting for Potential Confounders

The p-values for the blood pressure results in this study were unaffected after adjusting for differences in baseline characteristics that could potential confound these findings. The variables selected for adjusting the study results were entered as covariates in the MANOVA analysis model, which was identical to the univariate test of significance. The choice of covariates was based on the literature in the field and bivariate correlation significance between changes in blood pressure and body mass index, age, gender, alcohol consumption, smoking status, activity level, dietary sodium intake and urinary sodium excretion over the six week intervention. The only significant correlates were age, gender, BMI, and 24-hr urinary sodium excretion (Table 7).

Table 7. Bivariate Correlations Between Changes In Blood Pressure And Changes In Other Characteristics Known To Affect Blood Pressure

Characteristics	DBP-WK3 r-value	DBP-WK6 r-value	SBP-WK3 r-value	SBP-WK6 r-value
Age in years	.082	.221	.467**	.298
BMI (Baseline)	.119	.206	.079	.437**
Gender	.118	.161	.414**	.214
Urinary Sodium	.354*	.295	.337*	.337*
Exercise	.087	.092	.213	.102
Smoking (Yes or No)	.006	.126	.183	.021*
Dietary Sodium	.104	.154	.053	.154

* Correlation is significant at the 0.05 level (2-tailed).
** Correlation is significant at the 0.01 level (2-tailed).

Covariates found to be significantly correlated with the outcome variable were added as covariates in the MANOVA model during BP analysis. The One-Sample Kolmogorov-Smirnov Test was used in determining normality. The normality assumptions for the variables analyzed in this study were usually met.

The Mann-Whitney Test was used for study variables that did not meet the assumptions for the independent t-test.

D. Fruit Intake Results

Based on daily fruit records and food frequency questionnaires completed, the high fruit group appeared to have eaten the three fruits (bananas, raisins, orange juice) provided for their consumption during the six week intervention (Table 8). The control group appeared to have made little change in their dietary consumption of these fruit. Compared to the control group, the high fruit group had a net daily increase in bananas of 1.61 servings (95% confidence interval, 1.37 to 1.86; p<.001) , 1.54 boxes (1 ½ oz.) of raisins (95% confidence interval, 1.2 to 1.8; p<.001), and 3.75 servings of orange juice (6 oz.) (95% confidence interval, 1.55 to 2.33; p<.001). Overall, the intervention group, when compared with the control group exhibited a significant net increase in fruit intake of 6 servings per day (95% confidence interval, 5.59 to 7.04 servings; p<.001).

Table 8. Change (Six Week Follow-up Minus Baseline) in Dietary Fruit and Vegetable Intake During Intervention in 38 African Americans by Treatment Assignment

	Mean±SD			
Characteristic	Control (n= 19)	Cases (n=19)	Mean Difference	P-value
Dietary foods,				
Servings/day				
Bananas (medium)	.06±.16	1.7±.50	1.61 (1.37 to 1.86)	<.001**
Orange juice (6 oz.)	.11±.45	1.9±.82	1.99 (1.55 to 2.43)	<.001**
Raisins (1 ½ oz)	.	1.54±.55	1.54 (1.28 to 1.80)	<.001**
Fruit (1 piece, ½ cup)	.005±1.01	6.31±1.19	6.32 (5.59 to 7.04)	<.001**
Vegetable (½ cup)	.06±.79	.78±1.36	.85 (.11 to 1.58)	.025*

* Significant at .05 level
** Significant at .001 level

E. Fruit Intake Comparisons After Three Weeks

There were also important relationships between fruit intake per day during the intervention and changes in blood pressure levels (Table 9). Contrasting changes in systolic blood pressure after three weeks for the participants who consumed 1 or fewer servings of fruit per day (15 controls) with those who consumed 6 to 7 servings of fruit per day (7 cases), showed a significant decrease of 7.51 mm Hg in the higher fruit consumers (95% confidence interval, 1.73 to 13.29; p=.012). Comparing changes in systolic blood pressure for participants who consumed 1 or fewer servings of fruit per day with those who consumed 2 to 4 (4 controls) or 8 or more (15 cases) servings per day, were not statistically significant, but showed a trend in the right direction.

Table 9. Multiple Comparisons Between Fruit Intake and Changes in Systolic Blood Pressure During Intervention in 38 African Americans

Categories (I) of fruit intake	Categories (J) of fruit intake	Mean Difference (I-J) SBP (3 wk)	P-value	Mean Difference (I-J) SBP (6 wk)	P-value
1 or less servings/day and	2 to 4 servings/day	3.62 (-3.48 to 10.73)	.307	.298 (-7.31 to 7.91)	.937
	6 to 7 servings/day	7.51(1.73 to 13.29)	.012*	5.52 (-.66 to 11.72)	.078
	8 or more servings/day	3.66 (-1.22 to 8.55)	.137	6.04 (.80 to 11.28)	.025*
2 to 4 servings/day and	6 to 7 servings/day	3.89 (-4.02 to 11.80)	.327	5.23 (-3.24 to 13.70)	.219
	8 or more servings/day	.04 (-7.25 to 7.33)	.991	5.74 (-2.06 to 13.55)	.144
6 to 7 servings/day and	8 or more servings/day	3.85 (-2.15 to 9.85)	.201	.51(-5.91 to 6.95)	.871

* The mean difference is significant at the .05 level.

There was a net decrease in blood pressure of 3.62 mm Hg (95% confidence interval, 3.48 to 10.73; p=.307) for the study participants who consumed 2 to 4 servings of fruit per day and 3.66 mm Hg (95% confidence interval, 1.22 to 8.55; p=.137) for the study subjects who consumed 8 or more servings of fruit by mid-study.

Comparing changes in diastolic blood pressure after three weeks for participants who consumed 1 or fewer servings of fruit (15 controls) per day with those who consumed 6 to 7 servings of fruit (7 cases) per day, demonstrated a significant blood pressure decrease of 8.19 mm Hg in the participants who consumed higher levels of fruit (95% confidence interval, 3.06 to 13.32; p=.003) (Table 10).

Table 10. Multiple Comparisons Between Fruit Intake and Changes in Diastolic Blood Pressure During Intervention in 38 African Americans

Categories (I) ** of fruit intake	Categories (J) *** of fruit intake	Mean **** Difference (I-J) DBP (3 wk)	P-value	Mean **** Difference (I-J) DBP (6 wk)	P-value
1 or less servings/day and	2 to 4 servings/day	3.21(-3.08 to 9.52)	.937	2.69 (-3.85 to 9.25)	.409
	6 to 7 servings/day	8.19 (3.06 to 13.32)	.003*	4.42 (.90 to 9.76)	.101
	8 or more servings/day	1.88 (-2.45 to 6.22)	.383	4.27 (-.23 to 8.78)	.383
2 to 4 servings/day and	6 to 7 servings/day	4.98 (-2.04 to 12.00)	.159	1.73 (5.57 to 9.03)	.633
	8 or more servings/day	-1.33 (-7.79 to 5.13)	.697	3.31(-5.15 to 8.30)	.637
6 to 7 servings/day and	8 or more servings/day	6.31(.98 to 11.63)	.022*	-.15 (5.67 to 5.38)	.955

* The mean difference is significant at the .05 level.

There were no statistically significant changes in diastolic blood pressure after three weeks between the study participants who consumed 1 or fewer servings of fruit per day (15 controls) and those who consumed 2 to 4 servings of fruit (4 controls) per day. The net decrease in blood pressure in this comparison was 3.21 mm Hg in the higher fruit consumers (95% confidence interval, 3.08 to 9.52; p=.307). A comparison between the participants who ate 2 to 4 servings of fruit (4 controls) per day and those who ate 6 to 7 servings of fruit (7 cases) per day after three weeks revealed a net decrease in diastolic blood pressure of 4.9 mm Hg in the higher fruit consumers (95% confidence interval, 2.04 to 12.00; p=.159).

F. Fruit Intake Comparisons After Six Weeks

The changes in systolic blood pressure after six weeks for participants who consumed 1 or fewer servings of fruit per day (15 control) with those who consumed 8 or more servings of fruit per day (12 cases) revealed a statistically net decrease of 6.04 mm Hg in the high fruit consumers (95% confidence interval, .80 to 11.28; p=.025) (Table 9). Looking at changes in systolic blood pressure in this same time period for participants who consumed 1 or fewer servings of fruit per day with those who consumed 6 to 7 servings per day, revealed a non-significant net decrease of 3.04 mm Hg in the higher fruit consumers (95% confidence interval, .66 to 11.28; p=.078). In spite of the lack of statistical significance, the trend was in the right direction. Comparisons in systolic blood pressure for participants who consumed 2 to 4 servings of fruit per day with those who consumed 6 to 7 or 8 or more servings of fruit per day, showed non-significant net decreases of 5.23 mm Hg (95% confidence interval, -3.24 to 13.70; p=.219) and 5.74

mm Hg (95% confidence interval, 2.06 to 13.55; p=.144) respectively after six weeks.

Comparing changes in diastolic blood pressure after six weeks in participants who consumed 6 to 7 servings of fruit (7 cases) per day with those who consumed 8 or more servings of fruit (12 cases) per day revealed a significant net decrease in blood pressure of 6.31 mm Hg in the higher fruit consumers (95% confidence interval, .98 to 11.63; p=.022). There were no significant changes in diastolic blood pressure between those who consumed 1 or fewer servings of fruit per day (15 controls) and those who consumed 6 to 7 (7 controls) or 8 or more (12 cases) servings of fruit intake per day after six weeks. Despite the lack of significance, the trend was in the right direction. The blood pressure decreases in these two groups were 4.42 mm Hg (95% confidence interval, .90 to 9.76; p.101) and 4.27 mm Hg (95% confidence interval, .23 to 8.78; p>.06) respectively after week six (Table 10).

G. Dietary Nutrient Results

Based on food intake records, the high fruit group when compared with the control group during the intervention, exhibited a significant net increase in dietary potassium of 2037.78 mg (95% confidence interval, 1250.70 to 2824.87 mg; p<.001) and dietary magnesium of 113.07 mg (95% confidence interval, 36.67 to 189.47 mg; p=.005). (Table 11). Of the net increases in the above nutrients based on self report, 1,896.28 mg (95%) of potassium (95% confidence interval, 1696.03 to 2096.53 mg; p<.001) and 107.46 mg (95%) of magnesium (95% confidence interval, 96.25 to 118.67 mg; p<.001) can be attributed to dietary intakes of bananas, orange juice, and raisins during the 6 week intervention (Table 11). The change in dietary calcium intake of 62.22 mg (95%

confidence interval, 170.43 to 294.86; p=.591) and sodium intake of -754.34 mg (95% confidence interval, -667.80 to 2176.49; p=.289) over the course of the study was not significantly different between the controls and the cases (Table 11).

Table 11. Change (Six Week Follow-up Minus Baseline) in Dietary Nutrient Intake During Intervention in 38 African Americans by Treatment Group*

	Mean±SD			
Characteristic	Control (n= 19)	Cases (n=19)	Mean Difference	P-value
Dietary nutrients				
Potassium (mg)	311.56±1278.86	-1726.22±1107.32	2037.78 (1250.70 to 2824.87)	<.001**
Magnesium (mg)	19.33±132.21	-93.74±97.38	113.07 (36.67 to 189.94)	.005 *
Calcium (mg)	112.86±380.92	50.64±323.91	62.22 (170.43 to 294.86)	.591
Sodium (mg)	00.51±2447.29	1054.85±1831.21	-754.34 (-667.80 to 2176.49)	.289
Selected nutrients from bananas, raisins & orange juice combined				
Magnesium	-.18±10.33	-107.64±21.75	107.46 (96.25 to 118.67)	<.001**
Potassium	10.71±186.18	-1885.57±388.03	1896.28 (1696.04 to 2096.54)	<.001**

* Significant at .05 level
** Significant at .01 level

The Pearson Correlation test was used to identify significant bivariate correlations between changes in blood pressure and changes in dietary components over the course of the intervention. Significant nutrients identified included potassium, magnesium, sodium, and calcium. Significant dietary foods included overall fruit intake, bananas, orange juice and raisins (Tables 12 & 13).

sodium, and calcium. Significant dietary foods included overall fruit intake, bananas, orange juice and raisins (Tables 12 & 13).

Table 12. Correlations Between Changes in Blood Pressure and Changes in Dietary Nutrients During Intervention in 38 African Americans

Characteristics	SBP (3 wk) r-value	SBP (6 wk) r-value	DBP (3 wk) r-value	DBP (6 wk) r-value
Dietary Measures of				
Potassium	.393*	.401*	.407*	.264
Magnesium	.406*	.353*	.203	.218
Calcium	.375*	.166	.019	.048
Sodium	.104	.053	.033	.154

* Correlation is significant at the 0.05 level (2-tailed).
** Correlation is significant at the 0.01 level (2-tailed).

Table 13. Correlations Between Changes in Blood Pressure and Changes in Selected Dietary Foods During Intervention in 38 African Americans

Characteristics	SBP (3 wk) r-value	SBP (6 wk) r-value	DBP (3 wk) r-value	DBP (6 wk) r-value
Fruit	.345*	.391*	.247	.327*
Vegetables	.122	.082	.006	.122
Banana	.310	.475**	.222	.346*
Orange juice	.263	.344*	.180	.259
Raisins	.368*	.385*	.279	.385*

* Correlation is significant at the 0.05 level (2-tailed).
** Correlation is significant at the 0.01 level (2-tailed).

H. Urinary Nutrient Results

The mean difference in urinary levels of potassium, magnesium and sodium in the high fruit group when compared to the control group, were all statistically insignificant over the six week intervention (all p>.05) (Table 14.). Although urinary potassium changes were statistically insignificant for the cases (p=.07), the trend was in the right direction. The cases experienced a mean increase in urinary potassium excretion of 1017.62 mg compared with a mean increase of 199.39 mg in the controls. The net increase in potassium excretion in the cases over the controls was 818.23 mg. This finding though insignificant (problem due the small sample size) suggest that the experimental group did in fact increase there consumption of potassium rich foods. The statistically insignificant change in 24-hr urinary sodium excretion levels (p=.260) over the six week intervention validates that the study participants adhered to study protocol. They did not make significant changes in their sodium intake. Hence, a change in sodium intake is not the dietary factor responsible for the significant blood pressure effect in this study.

Table 14. Change (Six Week Follow-up Minus Baseline) in 24-hr. Urinary Nutrient Excretion During Intervention in 38 African Americans by Treatment Group*

	Mean±SD				
Characteristic	Control (n= 19) **	Cases (n=19) **	Mean Difference	95% Confidence Interval	P-value
24 hr. urinary values,					
Potassium	199.39±1421.57	1017.62±1343.98	-818.23	(92.00 to 1728.46)	.077
Sodium	-1049.22±2920.04	-340.07±1980.08	-709.15	(-1965.12 to 546.82)	.260
Calcium	-55.03±78.05	28.95±53.14	-26.08	(-70.01 to 17.85)	.236
Magnesium	-9.79±45.61	-10.71±42.93	.92	(-28.22 to 30.07)	.561

* All variables are shown as mean±SD unless otherwise indicated.
** All study participants are represented in each characteristic unless otherwise indicated.

Using the Pearson Correlation analysis, the change in diastolic blood pressure at mid-study and at end of study were significantly correlated with changes in urinary potassium excretion over the course of the six week study (r=.418; p=.009 and r=.397; p=.014 respectively) (Table 15). Significant bivariate correlations were also identified with changes in 24hr-urinary excretion rates for magnesium (r= -.340), sodium (r=.337 &.354), and calcium (r=.422 & .333) excretion. Magnesium was negatively associated with changes in blood pressure over the course of the intervention. The significant correlation between sodium excretion and blood pressure change was reflected in a net decrease in sodium excretion of -1049.22 mg in the controls and a net decrease of -340.07 mg in the cases. With regards to calcium excretion, the significant correlation was reflected in a net decrease in calcium of -55.03 mg in the controls and a net decrease of -28.95 mg in the cases.

Table 15. Correlations Between Changes in Blood Pressure and Changes in Urinary Characteristics During Intervention in 38 African Americans

Characteristics	SBP (3 wk) r-value	SBP (6 wk) r-value	DBP (3 wk) r-value	DBP (6 wk) r-value
Urinary Measures of				
Potassium	.203	.273	.418**	.397*
Magnesium	-.340*	.008	.095	.108
Sodium	.337*	.337*	.354*	.295
Calcium	.211	.422**	.165	.333*

* Correlation is significant at the 0.05 level (2-tailed).
** Correlation is significant at the 0.01 level (2-tailed).

CHAPTER 5

DISCUSSION

A. Introduction

The magnitude of the net reduction of 5.79 mm Hg systolic and 3.76 mm Hg diastolic in the cases over the controls in this six week intervention is note worthy given the average baseline blood pressure of 135/90 mm Hg. These blood pressure drops were similar in magnitude to the Guava fruit trials by Singh. et al. (1992 & 1993). Further, the net blood pressure reduction at week three (4.32/3.53) suggests that the blood pressure lowering effect of this dietary intervention was largely achieved by mid-study. The mean gross reduction in systolic and diastolic blood pressure for the high fruit group was 9.53 and 6.61 mm Hg respectively.

The net decrease in blood pressure for the experimental group when compared to the controls with mild hypertension was 14.42/4.85 mm Hg at week three and 12.59/6.53 mm Hg at week six. These results were twice the drop experienced when all the study participants in both groups were compared. These finding suggest that people with the highest blood pressure range may experience the greatest overall drop in blood pressure on a diet high in potassium rich fruits. Similar results in blood pressure change have been demonstrated by Appel, et al. (1997) who used potassium and magnesium rich foods to lower blood pressure in subject with high blood pressure.

The net decrease in systolic blood pressure after six weeks ($p=.131$) and the net decrease in diastolic blood pressure after three weeks ($p=.071$), were the only blood pressure results in the study participants with mild-hypertension that did not reach statistical significance. Since all data consistently have a trend in the right direction and approached significance, this result is likely due to the small sample size (Table 6).

While the treatment effect increased progressively during the 6-week intervention, it was more dramatic during the first three weeks (Figure 1 & 2). This difference cannot be accounted for by changes in fruit intake in the experimental group between the first 3 weeks and the last 3 weeks of this intervention. The cases reported a mean fruit intake of 6.8 servings/day during the first half of the intervention and a mean fruit intake of 7.9 servings/day during the second half of the intervention. The mean difference was -1.08 (-3.537 to 1.3714) with an insignificant p-value of .366. It appears that the main treatment effect of the high fruit diet was achieved within three weeks. This is similar to the DASH intervention trial, where the study participants experienced the largest drops in blood pressure after two weeks (Appel, et al. 1997).

B. Fruit Intake Data

The decrease in blood pressure in the experimental group was closely correlated to daily intake of bananas, orange juice, and raisins as reported by the study participants (Table 13). Of the net increases in dietary potassium and magnesium, 1896.28 mg (95%) of potassium (95% confidence interval, 1696.03 to 2096.53 mg; p<. 001) and 107.46 mg (94%) of magnesium (95% confidence interval, 96.25 to 118.67 mg; p<. 001) can be attributed to reported dietary intakes of bananas, orange juice and raisins during the 6 week intervention (Table 11). Given this information, it is likely that the treatment effect as represented by the above nutrients was largely due to the fruit supplements given to the cases.

The results of this study further suggest that daily fruit intake can have a direct effect on systemic blood pressure (Tables 9 & 10). The mean difference in fruit intake from 1 or fewer serving per day to just 2 to 4 servings per day resulted in blood pressure drops of 3.21 to 3.62 mm Hg. The mean difference in fruit intake from 2 to 4 servings per day and those who consumed 6 to 7 or 8 or more servings of fruit per day was even more pronounced. These blood pressure drops ranged between 3.04 to 8.19 mm Hg. The lack of significance in some of the fruit intake comparisons is likely due to the small sample. These results suggest that hypertensive individuals on a low fruit diet may benefit by increasing their daily intake of fruit that contain moderate to high levels of potassium and magnesium.

C. Dietary Nutrient Data

The dietary nutrients - magnesium and potassium were all significantly correlated to decreases in blood pressure during the intervention (Table 12). It has been suggested by Siani et al., (1987) that potassium supplementation in the amount of 48 mmols (1,877 mg) is sufficient to produce acceptable blood pressure lowering effects in hypertensive individuals. In our study, the mean increase in dietary potassium of 1,726.22 mg in the cases was similar to these suggested potassium supplement levels. Thus our results support the suggestion that a potassium increase of 1877 mg per day is an acceptable level to strive toward in hypertensive patients on low potassium diet.

The literature suggests that levels of magnesium intake may play a role in blood pressure control (Joffres et al., 1987 & Geleijnse et al., 1994). Based on dietary records, our study supports these findings (Tables 13 & 14). While the exact mechanism still needs to be determined, we stipulate that a synergistic blood pressure lowering effect was produced by the combination of magnesium, potassium and other yet unknown components of the fruit we provided for the study participants. Further study needs to elaborate on this finding.

D. Urinary Nutrient Data

The increase in urinary levels of potassium excretion in the cases (1017.62 mg) over the controls (199.39 mg) validates that the high fruit group did consume a much higher potassium diet during the intervention (Table 16). While this result did not reach statistical significance (p=.07), the trend was in the right direction. This borderline result is likely due to the small sample size. Bivariate correlations between changes in potassium excretion and diastolic blood pressure over the six-week intervention revealed an inverse relationship (Table 17).

The changes in the 24-hr magnesium excretion levels were insignificant (p=.561) over the course of the six week intervention. The controls had a mean decrease in magnesium excretion of -9.79 mg while the cases had a mean decrease of -10.71 mg of magnesium. This decrease in magnesium excretion may be do to low body stores of magnesium as a result of a compensatory conservation of magnesium by the kidneys (Gibson, 1990). While the mean 24-hr excretion levels for magnesium in our study population was 68 mg/24hr, normal urinary magnesium excretion ranges from 120 to 140 mg/24hr for persons on a mixed diet (Gibson, 1990).

The decrease in the 24-hr urinary excretion level of sodium in both cases and controls suggest that both groups decreased their daily intake of these nutrients. The mean decrease in urinary values for the case was approximately 1/3 (-340.07 mg) that of the controls (-1049.22 mg) (Table 16). Although the change in sodium excretion was not statistically significant over the course of the study, the net decrease in sodium excretion in the controls (709.15 mg) over the cases, gives a possible explanation for the significant decrease in blood pressure in the control group (Table 17). Further, the lack of significance in sodium excretion over the course of the study demonstrates that sodium was not responsible for the significant changes in blood pressure for the cases.

E. Methodological Strengths

Methodological strengths of our study include the use of electronic instruments for weight and blood pressure measurements, thus eliminating experimental bias and error. Providing the cases with a weekly supply of fruit rations increased the likelihood of compliance. Based on the daily fruit records in the cases, most of this group ate the fruit provided for them each week. The use of 24-hour urinary excretion rates to validate adherence to the dietary protocol was another strength of this intervention. We were able to determine that the study participant increased their intake of potassium rich foods, and that sodium intake was not significantly changed during the intervention.

F. Study Limitations

Potential limitations of the study also deserve comments. First, data from food frequency questionnaires are subject to participant errors in accurately estimating their intake of selected food items. Some study participants may have regularly eaten food items that were not listed on the food frequency questionnaire. A number of clients may have answered the questionnaire without giving much thought to their usual food intake.

Despite these concerns, the 24-hr urine samples enabled us to confirm that potassium levels were increased in the intervention group over the course of this study. Further, the change in sodium intake was not a significant factor in the blood pressure results. Even with this limitation, we were able to demonstrate significant and reliable outcomes.

Secondly, since the blood pressure measurements were largely taken after church services, the activity level during the service may have affected blood pressure measurements. However, since all the study participants were measured under very similar circumstances, the effects of the service were experienced in both groups, thus eliminating the possibility of biasing our findings.

Future research in this area should utilize a larger sample size, 24-hr recalls, three day food records and combinations of other fruits and food groups with similar profiles of potassium and magnesium. Three days food records and 24-hr recalls will enable the study subject to record their actual food intake rather than estimating their food consumption based on a food frequency questionnaire. Different combinations of various foods could be used to determine what foods are best able to lower blood pressure.

CHAPTER 6

SUMMARY AND RECOMMENDATIONS

A. Summary

This randomized dietary intervention trial examined the effects of increased daily consumption of bananas, orange juice and raisins on systemic blood pressure (BP) in 19 African-Americans. After six weeks, the mean systolic BP was 5.79 mm Hg (p=. 009) lower in the 19 cases than the 19 controls. The mean diastolic BP at six weeks was 3.76 mm Hg (p=. 047) lower in the cases than the controls. Analysis of the study participants who has mild hypertension, revealed a mean reduction in systolic and diastolic blood pressure after six weeks of 12.6 mm Hg (p=. 131) and 6.53 mm Hg (p=. 014) respectively in the cases when compared to the controls. All analysis included adjustments for BMI, activity level, alcohol intake, and changes in dietary sodium intake, and urinary sodium excretion over the six-week intervention.

B. Conclusions

The results of this study suggest that a diet high in potassium rich fruit such as bananas, orange juice and raisins is an effective approach to lowering blood pressure in individuals with mild hypertension who consume less than optimal levels of dietary potassium. Further, individuals with higher initial blood pressure readings may experience greater drops in blood pressure as a result of a high fruit intervention.

C. Implications to Preventive Care

Our data suggest that with a study group of borderline hypertensive individuals we can effectively utilize a dietary approach for the treatment of hypertension that focuses on increasing daily intakes of fruits and other foods that contain moderate to high amount of potassium and magnesium. The idea of focusing on adding tasty foods to the diet, rather than focusing on taking away foods that are satisfying will increase the likelihood of compliance, displacement of unhealthful food choices and long-term positive changes in health behaviors.

In addressing the hypertensive patient we may experience a more positive outcome if we include in the patient's assessment an analysis of dietary intakes of potassium and magnesium. Based on the DASH intervention trial, the target level for potassium and magnesium intake on 2000 Kcal/day is 4566 and 484 mg respectively (Appel, et al. 1997). If dietary intakes of these nutrients are less than optimal we should encourage the patients to increase their daily intake of foods containing moderate to high levels of these nutrients.

In practical terms we can begin by formulating a list of foods high in potassium and magnesium. Next we could group them in measured amounts that will provide a potassium intake of 10 to 12 mmols or 391 to 496 mg per each food item. Finally, based on the patient's potassium and magnesium intake we would encourage them to add to their present diet the number of servings required from the list of foods. The dietary goal based on our study is to increase their intake of potassium by at least 48 mmols or 1877mg per day.

Regarding dietary magnesium levels, the Preventive Care specialist could use the target level in the DASH study as a guideline.

yet effective method of reducing the burden of Hypertension in the world today. It is client friendly and requires minimal lifestyle changes. For the Preventive Care Specialist, this dietary approach to blood pressure control is an important treatment modalities that when applied appropriately, will reduce the blood pressure levels in hypertensive patients.

REFERENCES

Amstrong, B., Merwyk, J., & Coates, H. (1977). Blood pressure in seventh-day Adventist vegetarians. American Journal of Epidemiology, 105 (5), 444-449.

Appel, L., et al. (1997). A clinical trial of the effects of dietary patterns on blood pressure. The New England Journal of Medicine, 336 (16), 1117- 1124.

Ascherio, A., et al. (1996). Prospective study of nutritional factors, blood pressure, and Hypertension among U.S. women. Hypertension, 27 (5), 1065-1072.

Cappuccio, F., & Macgregor, G. (1991). Does potassium supplementation lower blood pressure? A meta-analysis of published trials. Journal Hypertension, 9, 465-473.

Cappuccio, F., Markandu, N., Beynon, G., Shore, A., Sampson, B., & Macgregor, B. (1985). Lack of effect of oral magnesium on high blood pressure: A double blind study. British Medical Journal, 291, 235-291.

Elliott, P., Dyer, A., & Stamler, R. (1989). The INTERSALT study: Results for 24 hour sodium and potassium, by age and sex. Journal of Human Hypertension, 3, 323-330.

Frisancho AR, Leonard WR, Bollettino LA. (1984). Blood pressure in blacks and whites and its relationship to dietary sodium and potassium intake. Journal of Chronic Diseases,37, 515-519.

Geleijnse, J., Grobbee, D., & Hofman, A. (1990). Sodium and potassium intake and blood pressure change in childhood. British Medical Journal, 300, 899-902.

Geleijnse, J., Witterman, J., Bak, A., Breeijen, J., & Grobbee. (1994). Reduction in blood pressure with a low sodium, high potassium, high magnesium salt in older subjects with mild to moderate hypertension. British Medical Journal, 309, 436-440.

Groen, J., Tijong, K., Koster, M., Willebrands, A., Verdonck, G., & Pierlott, M. (1962). The influence of nutrition and ways of life on blood cholesterol and the prevalence of hypertension and coronary heart disease among Trappist and Benedictine Monks. American Journal of Clinical Nutrition, 10, 456-470.

Harris, R., Phillips, R., Williams, P., Kuzna, J., & Fraser, G. (1981). The child-adolescent blood pressure study: The distribution of blood pressure levels in seventh-day adventist and non-seventh-day children. American Journal of Public Health, 71, 1342-1349.

Iacono, J., Puska, P., Dougherty, R., Pietinen, P., Leino, U., Mutanen, M., & Moisio, S. (1983). Effects of dietary fat on blood pressure in a rural Finish population. American Journal of Clinical nutrition, 38, 860-869.

INTERSALT Cooperative Research Group: INTERSALT: An international study of electrolyte and blood pressure. Results for 24 hour sodium and potassium excretion. British Medical Journal, 297, 319-328.

Langford, H., Blaufox M., Oberman, A., et al. (1985). Dietary therapy slows the return of hypertension after stopping medication. Journal of The American Medical Association, 253, 657-664.

Kaplan, NM, et al. (1985). Potassium supplement in hypertensive patients with diuretic-induced hypokalemia. The New England Journal of Medicine, 312;12, 746-749.

Krishna, GG., et al. (1989). Increased blood pressure during potassium depletion in normotensive men. The New England Journal of Medicine, 320, 18; 1177-1182.

Kromhout, D., Bosschieter, E., & Coulander, C. (1985). Potassium, calcium, alcohol intake and blood pressure: The zutphen study. The American Journal of Clinical Nutrition, 41, 1299-1304.

Lackland DT, Keil JE. (1996). Epidemiology of hypertension in African Americans. Semin Nephrol, 16, *2,* 63-70.

Little, P., Girling, G., Hasler, A., Trafford, A., & Craven, A. (1990). A controlled trial of a low sodium, low fat, high fibre diet in treated hypertensive patients: The efficacy of multiple dietary intervention. Postgraduate Medical Journal, 66, 616-621.

Margetts, B., Beilin, L., Armstrong, B., Rouse, I., Vandongen, R., Croft, K., & Mcmurchie, E. (1985). Blood pressure and dietary polyunsaturated and saturated fats: A controlled trial. Clinical Science, 69, 165-175.

Margetts, B., Beilin, D., Vandingen, R., & Armstrong, B. (1986). Vegetarian diet in mild hypertension: A randomized controlled trial. British Medical Journal, 293, 1468-1471.

Melby, C., Goldflies, D., Hyner, G., & Lyle, R. (1989). Relation between vegetarian and non-vegetarian diets and blood pressure in black and white adults. American Journal of Public Health, 79, 1283-1288.

Meneely GO, Battarbee H. (1976). High sodium-low potassium environments and hypertension. American Journal of Cardiology,38,768-785.

Matlou SM, Isles CG, Higgs A, Mine FJ, Murray GD, Schultz E & Starke IF. (1986). Potassium supplementation in blacks with mild to moderate essential hypertension. Journal of Hypertension, 4,1, 61-64.

Neaton, J., Brimm, R., Prineas, P., Stamler, J., Granadits, G., Elmer, P., Cuter, J., Fack, J., Schoenberger, J., Mcdonald, R., et al. (1993). Treatment of mild hypertension study. Final results. Journal of the American Medical Association, 270, 713-124.

Ophir, O., Peer, G., Gilad, J., Blum, M., & Aviram, A. (1993). Low blood pressure in vegetarians: The possible role of potassium. The American Journal of Clinical Nutrition, 37, 755-762.

Page LB, Vandervent DE, Nader K, Lubin NK, Page JR. (1981). Blood pressure of Qash=qai pastoral nomads in Iran in relation to culture, diet, and body form. American Journal of Clinical Nutrition, 34, 527-538.

Puska, P., Nissinen, A., Vartianinen, E., Dougherty, R., Mutanen, M., Iacono, J., Korhonen, H., Pietinen, P., Leino, U., & Moisio. (1983). Controlled, randomized trial of the effect of dietary fat on blood pressure. The Lancet, 1, 1-5.

Rabkin, S. (1994). Non pharmacologic therapy in the management of hypertension: An update. Canadian Journal of Public Health, 85, S44-S47.

Rouse, I., Armstrong, B., & Beilin, L. (1989). The relationship of blood pressure to diet and lifestyle in two religious population. Journal Hypertension, 1, 65-71.

Rouse, I., Armstrong, B., Beilin, L., & Vandongen. (1983). Blood pressure lowering effect of a vegetarian diet: Controlled trial in normotensive subjects. The Lancet, 1, 5-9.

Sacks, F., Rouse, I., Stampfer, M., Bishop, L., Lenherr, C., & Walter, R. (1987). Effect of dietary fats and carbohydrate on blood pressure of mild hypertensive patients. Hypertension, 10, 452-460.

Sacks, F., & Kass, E. (1988) Low blood pressure in vegetarians: Effects of specific foods and nutrients. American Journal of Clinical Nutrition, 48, 795-800.

Sacks, F., Rosner, B., & Kass, E. (1974). Blood pressure in vegetarian. American Journal of Epidemiology, 5, 390-398.

Sacks, F., Wood, P., & Kass, E. (1984). Stability of blood pressure in vegetarians receiving dietary protein supplements. Hypertension, 6, 199-201.

Sacks, F., Donner, A., Castelli, W., Gronemeyer, J., Pletka, P., Margolius, H., & Landsberg, E. (1981). Effect of ingestion of meat on plasma cholesterol of vegetarians. Journal of American Medical Association, 246, 640-644.

Sacks, F., Obarzanek, E., Windhauser, M,. et al.(1995). Rationale and design of the Dietary Approach to Stop Hypertension trial (DASH): a multi-center controlled feeding study of dietary patterns to lower blood pressure. Annals of Epidemiology, 5, 108-118.

Siani, A., Strazzullo, P., Giacco. A., Pacioni, D., Celentano, E., & Mancini, M. (1991). Increasing the dietary potassium intake reduces the need for antihypertensive medication. Annals of Internal medicine, 115, 753-759.

Singh, R., Sircar, S., Rastogi, S., & Singh, R. (1990). Dietary modulators of blood pressure in hypertension. European Journal of Clinical Nutrition, 44, 319-327.

Stamler, R., Stamler, J., Grimm, R., Gosch, F., Elmer, P., Dyer, A., Berman, R., Fishman, J., Heel, N., Civinelli, J., & Mcdonald, A. (1987). Final report of a four year randomized controlled trial: The hypertension control program. Journal of American Medical Association, 257, 1484-1491.

Appendix A - Permission Letters

INDEMNITY AGREEMENT

Ecclesia Christian Fellowship agrees to indemnify and hold harmless the Principle Investigator, Leonard L. Gibbons, all co-investigators, Loma Linda University, Loma Linda University Medical Center, Loma Linda University Faculty Medical Group, Inc. and their affiliates, trustees, officers, agents and employees ("The University") from any and all losses, expenses, claims, actions, lawsuits, and judgments including attorneys fees, which may be brought against the University by reason of personal injury, illness to or death of any person arising out of or connected with the performance of increased dietary intakes of fruits and vegetables being investigated pursuant to the Effects of Fruit and Vegetable Intake on System Blood Pressure in African Americans. Clinical Research Protocol (Effects of Fruit and Vegetable Intake on Systemic Blood Pressure in African Americans), provided, however, that any such loss, liability or damage resulting from (i) failure to adhere to the terms of the Protocols or Ecclesia Christian Fellowship written instruction relative to the use of fruits and vegetables, (ii) failure to comply with any application FDA, NIH or other governmental requirements, or (iii) acts of negligence or willful malfeasance (or misfeasance) by the University is excluded from this indemnity. In the event any such claim is made or lawsuit is initiated, the University shall promptly notify Ecclesia Christian Fellowship or receipt of notice of claim or the lawsuit in writing and shall cooperate fully in the defense of such lawsuit and shall permit Ecclesia Christian Fellowship or its insurance carrier to defend such claim or lawsuit.

EXECUTED as of the Jan day of 26, 199?

Ecclesia Christian Fellowship

By: Joshua Beckley

Title: Pastor

January 9, 1996

Mr. Leonard Gibbons
Loma Linda University
Office of Sponsored Research
11138 Anderson Street
Loma linda, CA 92350

Dear Mr. Gibbons:

On behalf of Ecclesia Christian Fellowship, we would like to thank you for your presentation on Hypertension to our congregation on Sunday, January 5, 1997. We understand the importance of the study you are conducting and we are more than happy to support and participate in this worthwhile endeavor.

Once again, thank you for giving Ecclesia Christian Fellowship the opportunity to participate in this study.

Yours Serving Him!

Joshua Beckley

Joshua Beckley
Senior Pastor

/do

1314 Date Street • San Bernardino, California 92404 • (909) 881-5551

INDEMNITY AGREEMENT

San Bernardino Christian Centre agrees to indemnify and hold harmless the Principle Investigator, Leonard L. Gibbons, all co-investigators, Loma Linda University, Loma Linda University Medical Center, Loma Linda University Faculty Medical Group, Inc. and their affiliates, trustees, officers, agents and employees ("The University") from any and all losses, expenses, claims, actions, lawsuits, and judgments including attorneys fees, which may be brought against the University by reason of personal injury, illness to or death of any person arising out of or connected with the performance of increased dietary intakes of fruits and vegetables being investigated pursuant to the Effects of Fruit and Vegetable Intake on System Blood Pressure in African Americans. Clinical Research Protocol (Effects of Fruit and Vegetable Intake on Systemic Blood Pressure in African Americans), provided, however, that any such loss, liability or damage resulting from (i) failure to adhere to the terms of the Protocols or San Bernardino Christian Centre written instruction relative to the use of fruits and vegetables, (ii) failure to comply with any application FDA, NIH or other governmental requirements, or (iii) acts of negligence or willful malfeasance (or misfeasance) by the University is excluded from this indemnity. In the event any such claim is made or lawsuit is initiated, the University shall promptly notify San Bernardino Christian Centre or receipt of notice of claim or the lawsuit in writing and shall cooperate fully in the defense of such lawsuit and shall permit San Bernardino Christian Centre or its insurance carrier to defend such claim or lawsuit.

EXECUTED as of the 28th day of January, 1997.

San Bernardino Christian Centre

By: Philip Ford Senior Pastor

Title:

The Centre

san bernardino christian centre

808 Commercenter West, Suite ... • P.O. Box 5220 • San Bernardino • California 92412-5220 • (909) 890-... • Fax (909) 890-...

January 28, 1997

Dr. Leonard Gibbons, M.P.H., Ph.D. (Cand.)
Office of Sponsored Research
Loma Linda University
11188 Anderson Street
Loma Linda, CA 92350

Dear Dr. Gibbons,

Thank you for the opportunity to meet with you and for the information provided on your research project. This letter serves as confirmation that we at San Bernardino Christian Centre are willing to be involved as full participants of the six week research project studying the relationship between diet and hypertension. I understand that we will be under the direction of the health professionals from Loma Linda University and that you, Dr. Gibbons, are the chief investigator as Preventive Care Specialist.

We also agree to hold harmless from liability the Loma Linda University, as members were recruited as willing participants through a survey process.

Thank you again for the opportunity to participate. We look forward to hearing from you about the results.

Yours truly,

Philip Powell, Senior Pastor
San Bernardino Christian Centre

PP:nis

Appendix B - Blood Pressure Protocol

Guidelines for Blood Pressure Measurements

Positioning the Person

1. Have the person seated comfortable, using the right arm with palm up, 1 hour after the last meal, 30 minutes after smoking or consumption of a caffeinated beverage, and 5 minutes prior to the first blood pressure measurement.
2. Instruct the person to relax, with feet flat on the floor and to sit straight in the chair.
3. Explain that BP will be taken 2 times even if normal because BP changes from minute to minute depending on what you have been doing.
4. Support the arm at mid-chest or heart level.
5. The BP operator should be in a position to see the manometer at eye level.

Applying the Cuff

1. The cuff should be applied to bare skin-all clothing should be pushed up or removed. The clothing should not be tight on the arm.
2. Measure for correct size.
   a) The width of the bladder should cover 40% of the arm circumference.
   b) The length of the bladder should cover at least 80% of the arm circumference.
   c) The cuff should cover 2/3 of the upper arm.
3. After finding the center of cuff's bladder (fold in half to find true center), position the cuff 1 inch above the elbow joint with it lining up with the palpated brachial artery.
4. Apply the cuff snugly around the arm (no more than two fingers should fit under cuff).

Estimating the Systolic Pressure

1. Find the radial pulse at the base of the thumb (do not use thumb to palpate).
2. Inflation and deflation of cuff while palpating the radial pulse should be quick and smooth (do not start and restart during inflation).
3. When you stop feeling the pulse, deflate slowly until the pulse is felt again, then completely deflate the cuff.

4. Record the point (mm Hg) where pulse disappeared on the line marked "radial pulse".
5. Wait 30 to 60 seconds before taking the BP reading.

Taking the Blood Pressure Reading

1. Put the stethoscope in your ears with ear tips placed forward and down.
2. Find the brachial pulse, and place the stethoscope there. Hold the entire diaphragm down with light pressure.
3. Close bulb valve, and rapidly fill the cuff with air to 30 mm Hg above estimated systolic BP, while maintaining a smooth continuous rate of inflation.
3. Read thee manometer at eye level.
4. Slowly open the valve. Let the air out slowly at 2 mm Hg per second. Listen for the beginning of the tapping sound and listen for the absence of the sounds.
5. Listen while going down at least 20 mm Hg below the last sound to ensure correct reading.
6. Then, open the valve completely, and remove the cuff.

Recording the Readings

1. Record systolic BP at the point of hearing the first of at least two regular consecutive K sounds.
2. Check to see how close this measurement is to the palpated estimated systolic pressure.
3. Record the diastolic BP as the last sound heard, i.e. the disappearance of sound: K5. Identify the BP reading as K4 if muffling occurs.
4. Record cuff size, ambient room temperature, initial position of the mercury in the manometer, and BP operators initials.
5. Take a second BP reading two minutes later and record the average of the two BP readings. If the two BP reading vary by more than 5 mm Hg take a third BP reading two minutes later.

This protocol is largely an adaptation from Labarthe, 1985, and C. Minks Grimm, 1988.

Three Day Blood Pressure Screening

Identification #____________________

Location: Temple Missionary Baptist Church, San Bernardino County

Name:__________________________________Sex:________ Age:______
Last First

Phone Number: (_____)___________ Height: ________ Weight: ______

First Blood Pressure Screening Date: _____/_____/_____
Radial pulse _______ Day Month Year

1. **If the average BP for the two reading is 130-169 mm Hg (systolic) and 85 -100 mm Hg (diastolic), and participant is otherwise eligible, proceed to next visit.**
2. **If blood pressure average is greater then the above ranges refer to counseling station.**

Reading #1:____/____ (Right Arm Seated) __________Screener's Initials
Reading #2:____/____ (Right Arm Seated) __________Screener's Initials
(2 minutes later) ____/____Average of two readings

Second Blood Pressure Screening Date: _____/_____/_____
Day Month Year

1. **If the average BP for the two screening visits is 130-165 mm Hg (systolic) and 85-99 mm Hg (diastolic), and participants is otherwise eligible, proceed to next visit.**
2. If blood pressure average is greater then the above ranges refer to counseling station.

Reading #1:____/____ (Right Arm Seated) __________Screener's Initials
Reading #2:____/____ (Right Arm Seated) __________Screener's Initials
(2 minutes later) ____/____Average of two readings

Third Blood Pressure Screening Date: _____/_____/_____
Day Month Year

1. **If the average BP for the three screening visits is 130-159 mm Hg (systolic) and 85-99 mm Hg (diastolic), and participants is otherwise eligible, proceed to study station.**
2. If blood pressure average is greater then the above ranges refer to counseling station.

Reading #1:____/____ (Right Arm Seated) __________Screener's Initials
Reading #2:____/____ (Right Arm Seated) __________Screener's Initials
(2 minutes later) ____/____Average of two readings

Three Day Average (Baseline) ____/____**Baseline Average**
Referral Information (check one): [ ] Study [ ] Counseling [ ] Normal BP

Appendix C - Study Eligibility

Give Us Six Weeks Of Your Time And Help Science
Take A Step Toward Controlling Hypertension

This six week research project is a study on the relationship between diet and hypertension. The chief investigator is Leonard L. Gibbons M.P.H., Dr. PH. (candidate). He is a Preventive Care Specialist from Loma Linda University. Health professional from Loma Linda University and members of the Temple Missionary Baptist Church Nursing Guild will work on the research team.

We need to recruit 100 African-American men and women who are:	**Yes**	**No**
▪ not currently being treated for hypertension	☐	☐
▪ not diabetics, no renal insufficiency and no special diets	☐	☐
▪ willing to increase their intake of selected fruits and vegetables	☐	☐
▪ willing to find out if they have hypertension	☐	☐
▪ 20-65 years old	☐	☐
▪ not seriously ill or pregnant/breast feeding	☐	☐

Why should you sign up for the study?
- Hypertension is a silent kill. *Most people who have it don't know they do.*
- Hypertension can lead to heart disease, stroke, and kidney disease.
- Nearly one in every three African American adults has hypertension.

What do we want from you?
- To answer a confidential questionnaire with questions about your health habits
- Two 24-hour urine samples for laboratory analysis (optional)
- Height, weight, blood pressure measurements and food intake records

What benefits will you get for participating ?
- Free analysis of your dietary habits and free food or food coupons
- Free counseling on controlling hypertension and free blood pressure checks
- A certificate of completion at the end of the study
- Knowing that your participation may improve hour health and benefit many others

If you agree to try out for this study please provide us with the following information:

Name ______________________________ Sex ______ Date ______________
(Last) (First) Day Month Year
Address ____
Telephone Number ______________ Age ________ Circle service attended: Early Mid-day

A member of the study team will screen participants for the following information:

Reading #1: ____ ____ (Right Arm Seated after 5 minutes) ____________________Screener
Reading #2: ____ ____ (Right Arm Seated 2 minutes later) ____________________Screener
Height _______ cm. Weight _________ kg. __________Average of two readings

Appendix D - Informed Consent

Loma Linda University

School of Public Health

"Informed Consent"

Loma Linda, California 92350
(909) 324-4546
FAX: (909) 324-4087

TITLE OF PROTOCOL

Effects of Fruit and Vegetable Intake on Systemic Blood Pressure in African-Americans

1. PURPOSE AND PROCEDURES

You are invited to participate in a research study because you are a health African-American who meets the following criteria: (1) you are not on a treatment program for hypertension; (2) you do not have diabetes or kidney disease, and are not on any special diet; (3) you are willing to find out if you have hypertension; (4) you are between the ages of 20 and 65; (5) you are not seriously ill or pregnant/breast feeding.

Participation in this study will take two weeks of screening activities followed by a six week intervention period. Participation in this study involves having two or three blood pressure reading on five separate Sundays over an eight week period, keeping daily food records, providing two 24-hour urine collections (optional), filling out two health questionnaires. Participation in this study will involve increasing dietary intakes of selected fruits and vegetables.

2. RISK

"The committee at Loma Linda University that reviews human studies (Institutional Review Board) has determined that participation in this study puts me to no risk."

3. BENEFITS

I have been told that the benefit to me is a reduction in blood pressure.

4. PARTICIPANTS' RIGHTS

I have been told that participation in this study in voluntary. My decision whether or not to participate or terminate at any time will not affect my present or future medical care.

5. CONFIDENTIALITY

I have been told that any published document resulting from this study will not disclose my identity without my permission.

First of 2 pages

LOMA LINDA UNIVERSITY

Loma Linda University

School of Public Health

Loma Linda, California 92350
(909) 824-4546
FAX: (909) 824-4087

6. ADDITIONAL COST
"There are no cost to me for participating in this study"

TITLE OF PROTOCOL
Effects of Fruit and Vegetable Intake on Systemic Blood Pressure in African-Americans

7. REIMBURSEMENT
"I have been told that I will receive free food items and a certificate of completion for participating in this study."

8. IMPARTIAL THIRD PARTY CONTACT
"I have been told that if I wish to contact an impartial party not associated with this study regarding any complaint I may have about the study, I may contact Jean Fankhanel, Patient Representative, Loma Linda University Medical Center, Loma Linda, CA 92354, phone (909) 824-4647 for information and assistance."

9. INFORMED CONSENT STATEMENT
"I have read the contents of the consent form and have listened to the verbal explanation given by the investigator. My questions concerning this study have been answered to my satisfaction. I hereby give voluntary consent to participate in this study. Signing this consent document does not waive my rights nor does it release the investigators, institution or sponsors from their responsibilities. I may call Leonard Gibbons M.P.H., Dr P.H. (candidate) at (909)796- 4138 if I have additional questions or concerns.

10. CONSENT COPY
"I have been given a copy of this consent form"

11. CALIFORNIA EXPERIMENTAL SUBJECTS'S BILL OF RIGHTS
"I have received a copy of the California Experimental Subject's Bill of Rights and have had these rights explained to me."

12. SIGNATURES

_______________________________ _______________
Signature of subject Date

____
Signature of witness

Second of 2 pages

A SEVENTH-DAY ADVENTIST HEALTH SCIENCES INSTITUTION

Appendix E - Blood Pressure Referral Guidelines

Referral Guidelines

Recommendations for Follow-up Based on Initial Set of Blood Pressure Measurements for Adults.

Category *	Systolic, mm Hg	Diastolic, mm Hg	Follow up Recommended
Normal	<130	<85	Recheck in 2 y
High normal +	130-139	85-89	Recheck in 1 y (Research)
Hypertension **			
Stage 1 (mild) +	140-159	90-99	Confirm within 2 mo (Research)
Stage 2 (moderate)	160-179	100-109	Evaluate and refer within 1 mo
Stage 3 (severe)	180-209	110-119	Evaluate and refer within 1 wk
Stage 4 (very severe)	=>210	=> 120	Evaluate and refer immediately

* Not taking antihypertensive drugs and not acutely ill

** Based on the average of two or more readings taken at each of two or more visits after an initial screening

\+ Categories that qualify for dietary intervention study after three separate reading dates

Source: 1993 *The Fifth Report of the J N C on Detection, Evaluation, and Treatment of High Blood Pressure*. Arch of Internal Medicine Vol 153, Jan 25, 154-182.

Note: All persons with BP levels in the moderate range or higher should be referred to their physician or a health care clinic for follow-up care.

Treatment Guidelines for Hypertension and/or CVD Risk Factors

Step 1 Lifestyle Modifications for Hypertension Control and/or Overall Cardiovascular Risk

- Lose weight if overweight.
- Limit alcohol intake to =<1 oz/d of ethanol (24 oz of beer, 8 oz of wine, or 2 oz of 100-proof whiskey)
- Exercise (aerobic) regularly
- Reduce sodium intake to less than 100 mmol/d (<2.3 g of sodium or less <6 g NaCl)
- Maintain adequate dietary potassium, calcium, and magnesium intake
- Stop smoking and reduce dietary saturated fat and cholesterol

Note: Use for stage 1 and stage 2 Hypertension during the first 3 to 6 months. If target organ disease (TOD) and/or other known risk factors for CVD are present and a BP less than 140/90 mm Hg has not been achieved start antihypertensive medication. If TOD and CVD risk factors are not present, some physicians may elect to withhold drug therapy with diastolic BP in the 90 to 94 mm Hg range and systolic BP in the 140 to 149 mm Hg range provided they give careful follow-ups at 3 to 6 month intervals.

Step 2 Continue Lifestyle Modifications/Initial Pharmacologic Selection:

- Diuretics or B-Blockers preferred. Reduction in morbidity & mortality demonstrated
- ACE Inhibitors, Calcium Antagonists, Alpha-Receptor Blockers, and Alpha-B-Blocker have not been tested nor shown to reduce morbidity and mortality

Note: Use for uncontrolled stage 1 and stage 2 hypertension after completion of step 1 guidelines and stages 3 and 4 hypertension.

Step 3 For Inadequate Responses

- Increase drug dose or
- Substitute another drug or
- Add 2nd agent for different class

Step 4 For Inadequate Responses

- Add 2nd or 3rd agent and/or
- Diuretic if not already prescribed

Source: 1993 *The Fifth Report of the JNC on Detection, Evaluation, and Treatment of High Blood Pressure*. Arch of Internal Medicine Vol 153, Jan 25, 154-183.

Appendix F - Physician Referral Letter

LOMA LINDA UNIVERSITY

Loma Linda University

School of Public Health

Loma Linda, California 92350
(909) 824-4546
FAX: (909) 824-4087

Referral Letter

Attention: ______________________________

This letter is in regards to a patient of yours. This individual was screened for the possibility of becoming a study participants in a clinical trial on diet and hypertension. They did not meet our study eligibility criteria. However, their blood pressure level after several measurements was high enough to warrant follow-up blood pressure measurements. We are referring this individual to you for follow-up. Thanks in advance for your help in this matter.

Individuals name: ______________________________

Blood Pressure: ________________

Sincerely,

____

Principle Investigator
Hypertension Study

Appendix G - Screening Flow Chart for Week 1

Screening Flowchart
Week one

CHECK-IN STATION
Direct church member to BP area; 8 persons per table
Sit for five minute rest

↓

MEASUREMENT STATION
* Use BP protocol; provide study screening forms to eligible persons; refer to counseling if needed; direct other persons out of screening room
Direct qualifying persons to height and weight station

↙ ↘

REFERRAL AND COUNSELING

Remeasure blood pressure;
refer to doctor or clinic for follow-up
if needed; provide counseling

HEIGHT AND WEIGHT

Record measurements on
screening form
Direct participants to check-out

↓

CHECK-OUT STATION

Review and file screening forms;
Encourage participants to return the following week

Appendix H - Instruction for 24-Hour Urine Collection

Instruction Sheet for 24-Hour Urine Collection

Dear participant:

We would like you to use the Saturday before the Sunday screening activity to collect your urine sample. It is better to keep the collection bottle in the refrigerator while you are collecting. The collection bottle contains acid, so be careful when you handle it so it will not spill on you. If it does, rinse the area thoroughly and immediately!

Instruction for collecting urine:

1. The morning of collection discard first void.
2. Collect the following voids throughout the day and night. You may want to void in cup and then transfer to the bottle.
3. Keep the urine refrigerated.
4. Collect the first void of the following morning.

If you have any questions or problems, please call Leonard Gibbons at (909) 796-4138 . Once you have completed your collection, you may deliver your sample to the designated area at the Church on Sunday morning.

THANKS YOU FOR YOUR COOPERATION!

Appendix I - Health Habits and History Questionnaire

HEALTH HABITS AND HISTORY QUESTIONNAIRE

This form asks you a variety of questions about your background, environment, and habits, which may affect or be related to your health. The information you provide will help scientists to understand more about the causes of disease.

This questionnaire will take about 40 minutes to complete. Please fill in the information requested, or place a check in the appropriate space. A few questions may be similar to ones you have answered before, but please do not skip any questions for this reason. If you are not sure about an answer, please estimate.

If you have any questions or would like help filling it out, please call ______________ at _____-_________. Please return this questionnaire by ____________________. We thank you for your time and your contribution to this research.

THIS SPACE FOR OFFICE USE

TODAY'S DATE: Month [|] - Day [|] - Year [|]
11 16

Please PRINT YOUR NAME (name of study participant)

[| | | | | | | | | | | | |] [| | | | | | | |] [| | | | | | | | |]
17 LAST 31 FIRST 40 MIDDLE

FEMALES: [| | | | | | | | | | | | | |]
49 MAIDEN 63

In what STATE (or country, if not U.S.) were you born? ______________________ 64 __ __ State Code

SOCIAL SECURITY NUMBER: ______ - ____ - ______
56 74

This information is completely voluntary. It will be used only to refer to statistical records maintained by the National Center for Health Statistics, in order to determine how health practices may be related to how long people live. For studies conducted by the National Institutes of Health, this information is collected under the authority of section 405(b)(1)(A) of the Public Health Service Act, 42 U.S.C. 284(b)(1)(A).

A __ 79 80

1-10*

ADDRESS: [| | | | | | | | | | | | | | | | | | | | | | |]
11 STREET 34

[| | | | | | | | | | | | |] [|] [| | | | | | | |]
35 CITY 49 STATE 52 ZIP 57

62 __ __ State Code

TELEPHONE: (_____) - _____ - ______
54 73

What is your relationship to the person enrolled in the study?

1____Self 2____Spouse 3____Relative 4____Other

__ 74

3 __ 79 80

Version 22.1, March, 1987 GEN ALL YR.2 -1-

PERSONAL INFORMATION, HABITS

11

1. When were you born? ______ / ______ / ______
   Month Day Year

2. How old are you? ___ years 18

3. Sex: 1 ___ Male 2 ___ Female 20

4. Race or ethnic background:
   1 ___ White, not of Hispanic origin 4 ___ American Indian/Alaskan native
   2 ___ Black, not of Hispanic origin 5 ___ Asian
   3 ___ Hispanic 6 ___ Pacific Islander 21

5. Please circle the highest grade in school you have completed:
   1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16+ 22

6. What is your marital status? 1 ___ Single 3 ___ Widowed
   2 ___ Married 4 ___ Divorced/Separated 24

7. How many times have you moved or changed residences in the last ten years? ___ times 25

8. Have you smoked at least 100 cigarettes in your entire life? 1 ___ No 2 ___ Yes If Yes, 27

   IF YES: About how old were you when you first started smoking cigarettes fairly regularly?
   ___ years old 28

   On the average of the entire time you smoked, how many cigarettes did you smoke per day?
   ___ cigarettes per day 30

   Do you smoke cigarettes now? 1 ___ No 2 ___ Yes 32
   IF NO: How old were you when you stopped smoking? ___ years old 33
   IF YES: On the average, about how many cigarettes a day do you smoke now? ___ cigarettes 35

9. Have you ever smoked a pipe or cigars regularly? 1 ___ No 2 ___ Yes If Yes, 37

   IF YES: For how many years? ___ years 38
   About how much? ___ pipes or cigars per ______________ 40
   (day or week)
   1 2

10. During the past year, have you taken any vitamins or minerals?
    1 ___ No 2 ___ Yes, fairly regularly 3 ___ Yes, but not regularly If Yes, 43

    What do you take fairly regularly? # of PILLS per DAY, WEEK, etc.

    Multiple Vitamins
    One-a-day type ______ pills per ______ 44
    Stress-tabs type ______ pills per ______ 47
    Therapeutic, Theragran type ______ pills per ______ 50

    Other Vitamins — How many milligrams or IU's per pill?
    Vitamin A ______ pills per ______ → ______ IU per pill 53
    Vitamin C ______ pills per ______ → ______ mg per pill 57
    Vitamin E ______ pills per ______ → ______ IU per pill 61
    Calcium or dolomite ______ pills per ______ → ______ mg per pill 65

    Other (What?) 1 ___ Yeast 2 ___ Selenium 3 ___ Zinc 4 ___ Iron 5 ___ Beta-carotene
    6 ___ Cod liver oil 7 ___ Other ______________ 69

    Please list the brand of multiple vitamin/mineral you usually take: ______________

-3-

FOR OFFICE USE
Q10. mg or IU 1 = 50-100 2 = 200-250 3 = 400-500 4 = 1000 5 = 5000 6 = 10,000 7 = 20,000-25,000 8 = 50,000 9 = Unk.

THIS PAGE FOR OFFICE USE

PLEASE GO TO NEXT PAGE

Information for coders:

Columns 1–10 are identical on each "card". They are omitted after page 1 but should be repeated on each card.

Col. 80 is blank on each card.

Enter number of the response which was checked (e.g., 1 for male, 2 for female).

For those questions in which a quantity is entered (e.g., years), code as entered.

?? = Not stated or Don't know. Leave no blanks. (Blanks are permitted in name and address fields on p. 1, and occupation field on p. 9).

P. 1. Col. [illegible]. Col. 62–63: Use state codes shown below

P. 1. Col. 11–17 Include century of birth: MM DD YYY.

P. 3. Q. 10: For each vitamin, code # pills in first two columns; code day, week, etc., in third column (1 = day, 2 = week, 3 = month, 4 = year); code mg/pill in fourth column, using codes shown at bottom of p. 3. If more than one "other vitamin" is checked, code = 5.

P. [illegible]: Code as shown on p. 4.

P. 7. Q. 14: Code first two columns of each food using codes at bottom of p. 7, or additional codes from codebook or database. Code remaining four columns as shown at bottom of p. 4.

P. 8. Col. 77–18: No–Yes in 1st column; # times in 2nd col. (8 = 8 or more); age in 3rd–4th col.

P. 8. Col. 46–47, 50–51: Use codes at bottom of p. 8.

State codes:

01 AL Alabama	13 ID Idaho	25 MS Mississippi	37 OK Oklahoma	49 WV West Virginia
02 AK Alaska	14 IL Illinois	26 MO Missouri	38 OR Oregon	50 WI Wisconsin
03 AZ Arizona	15 IN Indiana	27 MT Montana	39 PA Pennsylvania	51 WY Wyoming
04 AR Arkansas	16 IA Iowa	28 NE Nebraska	40 RI Rhode Island	52 PR Puerto Rico
05 CA California	17 KS Kansas	29 NV Nevada	41 SC South Carolina	53 VI Virgin Islands
06 CO Colorado	18 KY Kentucky	30 NH New Hampshire	42 SD South Dakota	54 GU Guam
07 CT Connecticut	19 LA Louisiana	31 NJ New Jersey	43 TN Tennessee	55 Canada
08 DE Delaware	20 ME Maine	32 NM New Mexico	44 TX Texas	56 Cuba
09 DC District of Col.	21 MD Maryland	33 NY New York	45 UT Utah	57 Mexico
10 FL Florida	22 MA Massachusetts	34 NC North Carolina	46 VT Vermont	59 Remainder of World
11 GA Georgia	23 MI Michigan	35 ND North Dakota	47 VA Virginia	99 Unknown or blank
12 HI Hawaii	24 MN Minnesota	36 OH Ohio	48 WA Washington	

Information for proper use of analysis program:

For use with the Personal Computer analysis program, the questionnaire must be keyed in 80-column lines, with the ID field in columns 1–10 of each line, and a line-identifying letter in column 79 of each line, starting with "A" and progressing evenly upward. For use with the mainframe program, the ID and line-ID requirements are less rigid. See Health Habits and History Questionnaire information package for further instructions.

Version [illegible] of this questionnaire (this version) differs slightly from earlier versions. To use the diet analysis program with this version, you must select the "Nonstandard" option (STANDQ = N), and provide the program with the following information, when prompted:

Number of characters = [illegible]

Position of variables	Card	Col.		Card	Col.		Card	Col.
Name	A	17	Amt. of weight change	[illegible]	67	Type of cooking fat	[illegible]	54
Age	C	13	First special diet	C	70	Fat on vegetables	[illegible]	56
Sex	C	20	Second special diet	C	71	Intake of vitamins	C	43
Height (ft.)	[illegible]	43	Whether eats skin	[illegible]	47	Intake of multiple vits.	C	44
Height (in.)	[illegible]	44	Whether eats fat	[illegible]	48	Intake of single vits.	C	53
Weight	[illegible]	46	Freq. of cooking fat	[illegible]	51	Intake of other vits.	C	69
Weight change	[illegible]	68	Unit of cooking fat	[illegible]	53	Types of restaurants	C	72

In addition, if you set VEGADJ = Y, tell it J61 when prompted.
In addition, if you set ADDSALT = Y, tell it J49 when prompted.
In addition, if you set COLDCER = Y, tell it J58 when prompted.
In addition, if you set FRTADJ = Y, tell it J64 when prompted.

Number of food fields = 12

Field	Card	Col.	# foods	Field	Card	Col.	# foods	Field	Card	Col.	# foods
[illegible]	[illegible]	[illegible]	13	[illegible]	[illegible]	[illegible]	[illegible]	9	[illegible]	59	5
[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	31	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
4	[illegible]	57	4	8	[illegible]	59	[illegible]	[illegible]	[illegible]	43	5

All [illegible] foods included? No

Number not included = [illegible] Which ones = [illegible]

Number of extra foods = [illegible]

[illegible] Food: Card [illegible] col. [illegible] Food code: Card [illegible] col. [illegible]
[illegible] Food: Card [illegible] col. [illegible] Food code: Card [illegible] col. [illegible]
[illegible] Food: Card [illegible] col. [illegible] Food code: Card [illegible] col. [illegible]

Number of open-ended foods = [illegible] Open-ended information starts in Card [illegible] col. [illegible]

If you modify this questionnaire, you must change the above variables to correspond with your revised version.

11. Are you on a special diet?	**OFFICE USE**
1 ___ No 2 ___ Weight loss 3 ___ For medical condition 4 ___ Vegetarian 5 ___ Low salt	
6 ___ Low cholesterol 7 ___ Weight gain	70 __ __

12. How often do you eat the following foods from *restaurants* or *fast food places*?

RESTAURANT FOOD	1 Almost every day	2 2-4 times a week	3 Once a week	4 1-3 times a month	5 5-10 times a year	6 1-4 times a year	7 Never, or less than once a year	OFFICE USE
Fried chicken								72 __
Burgers								73 __
Pizza								74 __
Chinese food								75 __
Mexican food								76 __
Fried fish								77 __
Other foods								78 __

13. This section is about your *usual* eating habits. Thinking back over the past year, how often do you usually eat the foods listed on the next page?

C 79 80

First, check (✓) whether your usual serving size is small, medium or large. (A small portion is about one-half the medium serving size shown, or less; a large portion is about one-and-a-half times as much, or more.)

Then, put a *NUMBER* in the most appropriate column to indicate *HOW OFTEN*, on the average, you eat the food. You may eat bananas *twice a week* (put a 2 *in the "week"* column). If you never eat the food, check "Rarely/Never." Please DO NOT SKIP foods. And please BE CAREFUL which column you put your answer in. It will make a big difference if you say "Hamburger once a day" when you mean "Hamburger once a week"!

Some items say "in season." Indicate how often you eat these just in the 2-3 month time when that food is in season. (Be careful about overestimating here.)

Please look at the *example* below. This person

1) eats a medium serving of cantaloupe once a week, in season.

2) has ½ grapefruit about twice a month.

3) has a small serving of sweet potatoes about 3 times a year.

4) has a large hamburger or cheeseburger or meat loaf about four times a week.

5) never eats winter squash.

EXAMPLE:

	Medium Serving	Your Serving Size S	M	L	How often? Day	Week	Month	Year	Rarely/ Never
Cantaloupe (in season)	¼ medium		✓			1			
Grapefruit	(½)		✓				2		
Sweet potatoes, yams	½ cup	✓						3	
Hamburger, cheeseburger, meat loaf	1 medium		✓			4			
Winter squash, baked squash	½ cup								✓

PLEASE GO TO NEXT PAGE →

FOR OFFICE USE

On the following two pages, code the four characters for each food as follows:

S-1	No.	Day-1
M-2	Times	Wk-2
L-3		Mo-3
NS-4	NS-9	Yr-4
		Nev-5
		NS-9

If respondent places a checkmark in the "How often" column, do not impute "01" once. Instead, code "99". Not Stated: if respondent does not check a portion size, do not impute medium, but code "9".

	Medium Serving	Your Serving Size S	M	L	Day	Week	Month	Year	Rarely/ Never	OFFICE USE
FRUITS & JUICES		S	M	L						
EXAMPLE - Apples, applesauce, pears	(1) or ½ cup		✓			4				
Apples, applesauce, pears	(1) or ½ cup									11 ____
Bananas	1 medium									15 ____
Peaches, apricots (canned, frozen or dried, whole year)	(1) or ½ cup									19 ____
Peaches, apricots, nectarines (fresh, in season)	1 medium									23 ____
Cantaloupe (in season)	¼ medium									27 ____
Watermelon (in season)	1 slice									31 ____
Strawberries (fresh, in season)	½ cup									35 ____
Oranges	1 medium									39 ____
Orange juice or grapefruit juice	6 oz. glass									43 ____
Grapefruit	(½)									47 ____
Tang, Start breakfast drinks	6 oz. glass									51 ____
Other fruit juices, fortified fruit drinks	6 oz. glass									55 ____
Any other fruit, including berries, fruit cocktail	½ cup									59 ____
VEGETABLES		S	M	L	Da	Wk	Mo	Yr	Nv	
String beans, green beans	½ cup									63 ____
Peas	½ cup									67 ____
Chili with beans	¾ cup									71 ____
Other beans such as baked beans, pintos, kidney beans, limas	¾ cup									75 ____ D 79 80
Corn	½ cup									11 ____
Winter squash, baked squash	½ cup									15 ____
Tomatoes, tomato juice	(1) or 6 oz.									19 ____
Red chili sauce, taco sauce, salsa picante	2 Tblsp. sauce									23 ____
Broccoli	½ cup									27 ____
Cauliflower or brussel sprouts	½ cup									31 ____
Spinach (raw)	¾ cup									35 ____
Spinach (cooked)	½ cup									39 ____
Mustard greens, turnip greens, collards	½ cup									43 ____
Cole slaw, cabbage, sauerkraut	½ cup									47 ____
Carrots, or mixed vegetables containing carrots	½ cup									51 ____
Green salad	1 med. bowl									55 ____
Salad dressing, mayonnaise (including on sandwiches)	2 Tblsp.									59 ____
French fries and fried potatoes	¾ cup									63 ____
Sweet potatoes, yams	½ cup									67 ____
Other potatoes, including boiled, baked, potato salad	(1) or ½ cup									71 ____
Rice	¾ cup									75 ____ E 79 80
Any other vegetable, including cooked onions, summer squash	½ cup									11 ____
Butter, margarine or other fat on vegetables, potatoes, etc.	2 pats									15 ____
MEAT, FISH, POULTRY & MIXED DISHES		S	M	L	Da	Wk	Mo	Yr	Nv	
Hamburgers, cheeseburgers, meat loaf	1 medium									19 ____
Beef—steaks, roasts	4 oz.									23 ____
Beef stew or pot pie with carrots, other vegetables	1 cup									27 ____
Liver, including chicken livers	4 oz.									31 ____
Pork, including chops, roasts	2 chops or 4 oz.									35 ____
Fried chicken	2 sm. or 1 lg. piece									39 ____
Chicken or turkey, roasted, stewed or broiled	2 sm. or 1 lg. piece									43 ____
Fried fish or fish sandwich	4 oz. or 1 sand.									47 ____
Tuna fish, tuna salad, tuna casserole	½ cup									51 ____
Shell fish, shrimp, lobster, crab, oysters, etc	(5) ¼ cup or 3 oz									55 ____
Other fish, broiled, baked	4 oz.									59 ____
Spaghetti, lasagna, other pasta with tomato sauce	1 cup									63 ____
Pizza	2 slices									67 ____
Mixed dishes with cheese, such as macaroni and cheese	1 cup									71 ____

	Medium Serving	Your Serving Size	How often	Office Use	
LUNCH ITEMS		S M L			
Liverwurst	2 slices			75 _____	F 79 80
Hot dogs	2 dogs			11 _____	
Ham, lunch meats	2 slices			15 _____	
Vegetable soup, vegetable beef, minestrone, tomato soup	1 med. bowl			19 _____	
Other soups	1 med. bowl			23 _____	
BREADS, SALTY SNACKS, SPREADS		S M L	Da Wk Mo Yr Nv		
Biscuits, muffins, burger rolls (incl. fast foods)	1 med. piece			27 _____	
White bread (including sandwiches), bagels, etc., crackers	2 slices, 3 cracks			31 _____	
Dark bread, including whole wheat, rye, pumpernickel	2 slices			35 _____	
Corn bread, corn muffins, corn tortillas	1 med. piece			39 _____	
Salty snacks (such as chips, popcorn)	2 handfuls			43 _____	
Peanuts, peanut butter	2 Tbsp.			47 _____	
Butter on bread or rolls	2 pats			51 _____	
Margarine on bread or rolls	2 pats			55 _____	
Gravies made with meat drippings, or white sauce	2 Tbsp.			59 _____	
BREAKFAST FOODS		S M L	Da Wk Mo Yr Nv		
High fiber, bran or granola cereals, shredded wheat	1 med. bowl			63 _____	
Highly fortified cereals, such as Product 19, Total, or Most	1 med. bowl			67 _____	
Other cold cereals, such as Corn Flakes, Rice Krispies	1 med. bowl			71 _____	
Cooked cereals	1 med. bowl			75 _____	G 79 80
Sugar added to cereal	2 teaspn.			11 _____	
Eggs (1 egg = small, 2 eggs = medium)				15 _____	
Bacon	2 slices			19 _____	
Sausage	2 patties or links			23 _____	
SWEETS		S M L	Da Wk Mo Yr Nv		
Ice cream	1 scoop			27 _____	
Doughnuts, cookies, cakes, pastry	1 pc. or 3 cookies			31 _____	
Pumpkin pie, sweet potato pie	1 med. slice			35 _____	
Other pies	1 med. slice			39 _____	
Chocolate candy	small bar, 1 oz.			43 _____	
Other candy, jelly, honey, brown sugar	3 pc. or 1 Tbsp.			47 _____	
DAIRY PRODUCTS		S M L	Da Wk Mo Yr Nv		
Cottage cheese	½ cup			51 _____	
Other cheeses and cheese spreads	2 slices or 2 oz.			55 _____	
Flavored yogurt	1 cup			59 _____	
Whole milk and bevs. with whole milk (not incl. on cereal)	8 oz. glass			63 _____	
2% milk and bevs. with 2% milk (not incl. on cereal)	8 oz. glass			67 _____	
Skim milk, 1% milk or buttermilk (not incl. on cereal)	8 oz. glass			71 _____	
BEVERAGES		S M L	Da Wk Mo Yr Nv		
Regular soft drinks	12 oz. can or bottle			75 _____	H 79 80
Diet soft drinks	12 oz. can or bottle			11 _____	
Beer	12 oz. can or bottle			15 _____	
Wine	1 med. glass			19 _____	
Liquor	1 shot			23 _____	
Decaffeinated coffee	1 med. cup			27 _____	
Coffee, not decaffeinated	1 med. cup			31 _____	
Tea (hot or iced)	1 med. cup			35 _____	
Lemon in tea	1 teaspn.			39 _____	
Non-dairy creamer in coffee or tea	1 Tbsp.			43 _____	
Milk in coffee or tea	1 Tbsp.			47 _____	
Cream (real) or half and half in coffee or tea	1 Tbsp.			51 _____	
Sugar in coffee or tea	1 teaspn.			55 _____	
Artificial sweetener in coffee or tea	packet			59 _____	
Glasses of water, not counting in coffee or tea	8 oz. glass			63 _____	

67 2 2 2 2 2 2 . . . I 79 80

- Think about your diet over the last year and the responses you have just made on this questionnaire. Are there any foods not mentioned which you ate at least once a week, even in small quantities, or ate frequently in a particular season? Consider other meats, breakfast foods, catsup, green chilies or jalapenos, avocado (guacamole), Mexican dishes, Chinese or other ethnic foods, other fruits or vegetables, as well as nutritional supplements (bran, etc.). *Please take a look at the list of foods at the bottom of the page.*

FOOD	Your Serving Size S	M	L	How Often? Day	Week	OFFICE USE Code	Amount
						11	
						17	
						23	
						29	
						35	
						41	

	1 Seldom/Never	2 Sometimes	3 Often/Always	
15. How often do you eat the skin on chicken?	____	____	____	47 _
How often do you eat the fat on meat?	____	____	____	48 _
How often do you add salt to your food?	____	____	____	49 _
How often do you add pepper to your food?	____	____	____	50 _

16. How often do you use fat or oil in cooking?
For example, in frying eggs, meat or vegetables? ____ times per ________ (day, week, month) — 51 _ _ _

17. What do you *usually* cook with? 1 __ Don't know or don't cook 2 __ Soft margarine
3 __ Stick margarine 4 __ Butter 5 __ Oil 6 __ Lard, fatback, bacon fat
7 __ Pam or no oil — 54 _ _

18. What kind of fat do you *usually* add to vegetables, potatoes, etc?
1 __ Don't add fat 2 __ Soft margarine 3 __ Stick margarine 4 __ Butter
5 __ Half butter, half margarine 6 __ Lard, fatback, bacon fat — 56 _

19. If you eat cold cereal, what kind do you eat most often? ________________ — 58 _

20. Not counting salad or potatoes, about how many
vegetables do you eat per day or per week? ____ (vegetables) per ____ (day, week) — 61 _

21. Not counting juices, how many fruits do you
usually eat per day or per week? ____ (fruits) per ____ (day, week) — 64

22. Have you gained or lost more than five pounds in the past year? (You may check more than one answer.)
1 __ No 2 __ Lost 5-15 lbs. 3 __ Lost 16-25 lbs. 4 __ Lost more than 25 lbs. — 67
5 __ Gained 5-15 lbs. 6 __ Gained 16-25 lbs. 7 __ Gained more than 25 lbs.
68

-7-

DO YOU EAT THESE ONCE A WEEK?

veal, lamb	[illegible]	pancakes, waffles	[illegible]	onions	41	Hi-C
tofu	33	instant breakfast, Nutrament	[illegible]	summer squash	[illegible]	cranberry juice [illegible]
mixed dish – meat	34	pudding	[illegible]	asparagus	[illegible]	grapes
mixed dish – chicken	35	milkshake	[illegible]	sweet green peppers	[illegible]	tangerines
Chinese dishes	36	other dairy product	[illegible]	sweet red peppers	[illegible]	papayas
Mexican dishes	37	other dessert, sweet	[illegible]	bean sprouts	[illegible]	honeydew or casaba
seafood stew	38	sour cream, dips	[illegible]	avocado, guacamole	[illegible]	lemons or lemon
refried beans or bean burritos	39	diet salad dressing	[illegible]	beets	[illegible]	nuts and seeds
Polish or Italian sausage	[illegible]	catsup	[illegible]	pineapple or pineapple juice	51	bran
cream soups	[illegible]	green chilies, jalapenos	[illegible]	prunes or prune juice	52	other vegetable [illegible]
noodles	[illegible]					other not mentioned

OTHER HEALTH FACTORS

OFFICE USE

31. How tall are you? ____ feet ____ inches   32. How much do you weigh? ____ pounds   43 ______

33. What is the most you have ever weighed? ____ pounds   49 ___

34. About how many times have you gone on a diet to lose weight?

(1) ___ Never   (2) ___ 1-2   (3) ___ 3-5   (4) ___ 6-8   (5) ___ 9-11   (6) ___ 12 or more times   52 _

35. How many hours of sleep do you usually get at night?

(1) ___ 6 hours or less   (2) ___ 7 hours   (3) ___ 8 hours   (4) ___ 9 hours or more   53 _

36. How often do you feel under stress which makes you tense or worried, or causes physical problems such as stomach or back trouble or headaches?

(1) ___ Every day   (2) ___ Several times a week   (3) ___ Several times a month   (4) ___ Several times a year   (5) ___ Rarely or never   54 _

37. Here is a list of active things that people do in their free time. How often do you do any of these things?

	1 MORE THAN ONCE A WEEK	2 ABOUT ONCE A WEEK	3 A FEW TIMES A MONTH	4 A FEW TIMES A YEAR	5 RARELY OR NEVER	
Active sports	____	____	____	____	____	55 _
Doing physical exercises	____	____	____	____	____	56 _
Jogging or running	____	____	____	____	____	57 _
Swimming or taking long walks .	____	____	____	____	____	58 _
Gardening, fishing, hunting . . .	____	____	____	____	____	59 _
Something else__________ . .	____	____	____	____	____	60 _

38. How many close friends do you have? (People that you feel at ease with, can talk to about private matters, and can call on for help.)

(1) ___ None   (2) ___ 1 or 2   (3) ___ 3 to 5   (4) ___ 6 to 9   (5) ___ 10 or more   61 _

How many relatives do you have that you feel close to?

___ None   ___ 1 or 2   ___ 3 to 5   ___ 6 to 9   ___ 10 or more   62 _

How many of these friends or relatives do you see or talk to at least *once a month*?

___ None   ___ 1 or 2   ___ 3 to 5   ___ 6 to 9   ___ 10 or more   63 _

39. How often do you participate in the following groups or activities?

	1 MORE THAN ONCE A WEEK	2 ABOUT ONCE A WEEK	3 A FEW TIMES A MONTH	4 A FEW TIMES A YEAR	5 RARELY OR NEVER	
Go to church or temple	____	____	____	____	____	64 _
Participate in group meetings or activities (such as clubs, PTA, professional, labor or service groups)	____	____	____	____	____	65 _

Please take a moment to fill in any questions you may have skipped.   Version # __ __

THANK YOU VERY MUCH for taking the time to fill out this information. The answers you have given will be very useful in interpreting the results of this study, and in helping to understand and control disease. Your participation is sincerely appreciated.   Coder __ __

Reviewed by ______________________

Appendix J - Screening Flowchart Week 2

Screening Flowchart
Week two

CHECK-IN STATION
Direct church member to BP area; 8 persons per table
Sit for five minute rest

MEASUREMENT STATION
* Use BP protocol; provide study screening forms to eligible persons; refer to counseling if needed; direct other persons out of screening room
* Provide instruction and guidance for filling out the HHHQ
Direct qualifying individuals to height and weight station

REFERRAL AND COUNSELING

Remeasure blood pressure;
refer to doctor or clinic for follow-up
if needed; provide counseling

HEIGHT AND WEIGHT

Record measurement on
screening form and HHHQ;
Direct participants to check-out

CHECK-OUT STATION

Review and file HHHQ forms and other screening forms;
Encourage participants to return the following week

Appendix K - Group B Food Diary

Food Diary Instructions for group B:

Add up and record the total number of servings of the following foods you eat each day. **Do not change your eating habits.**

Food Diary for Week 1

SERVING SIZE	FRUIT	SUN	MON	TUES	WED	THURS	FRI	SAT	Week Total
1 medium	banana								
1 or 6 oz	orange/juice								
½ cup or 6 oz	pineapple/juice								
1	tangerine								
½ cup or 6 oz	grapes/juice								
1 or 6 oz.	apple/juice								
	Daily Total								
1 cup	MILK								
	Daily Total								
1 egg	EGGS								
	Daily Total								
SERVING SIZE	VEGETABLES	SUN	MON	TUES	WED	THURS.	FRI	SAT	Week Total
1	potato-bake/boil								
½ cup	spinach								
½ cup	pumpkin								
½ cup	broccoli								
½ cup	green peas								
½ cup	green beans								
½ cup	sweet potato								
½ cup	turnip greens								
½ cup	kale								
½ cup	mustard greens								
1 medium	tomatoes								
	Daily Total								
4 oz	BEEF								
4 oz.	PORK								
1 piece	CHICKEN								
	Daily total								

Appendix L - Group A Food Diary

Food Diary Instructions for group A:

The food selections on top of the fruit and vegetable list have the highest amounts of potassium and magnesium. Choose them more frequently. You will be given six servings of fruit for each day. You do not have to eat additional fruit. Add up and record the total number of servings of fruit and vegetables you eat each day and the weeks total.

Fruit and Vegetable Diary for Week 1									
Your goal for fruit per week is 42 servings					Your goal for vegetables per week is 21-35				
SERVING SIZE	FRUIT 6 servings per/day	SUN	MON	TUES	WED	THURS.	FRI	SAT	Week Total
1 medium	banana								
6 oz. glass	orange juice								
1 ½ oz.	raisins								
1 or 6 oz. glass	pineapple/juice								
1	nectarine								
1 or 6 oz. glass	apple/ juice								
1	tangerine								
½ cup or 6 oz	grapes/juice								
½	grapefruit								
	Days total								
SERVING SIZE	VEGETABLES 3 TO 5 servings/day	SUN	MON	TUES	WED	THURS.	FRI	SAT	Week Total
1 medium	potato-bake/boil								
½ cup	spinach								
½ cup	pumpkin								
½ cup	broccoli								
½ cup	green peas								
½ cup	green beans								
½ cup	sweet potato								
½ cup	turnip greens								
½ cup	kale								
½ cup	mustard greens								
1 medium	tomatoes								
½ cup	okra								
½ cup	corn								
	Days total								

Appendix M - Screening Flow Chart Week 3

Screening Flowchart
Week three